

Industry Sponsored Clinical Trial Agreements

Financial Considerations

Financial Considerations

- Study Budget
- Payment Terms

Study Budget

- Study Budget
 - Internal Budget Development
 - Budget Negotiations with Sponsor

Study Budget

- Study Budget
 1. Internal Budget Development
 2. Budget Negotiations with Sponsor

Study Budget

Internal Budget Development

The process of identifying all of the expenses associated with participating in a clinical trial.

- Coverage Analysis
- Internal Charges identified
- Time and Effort Assessment
- Additional Costs identified

Study Budget

Internal Budget Development

Coverage Analysis

- First step should always be to perform a coverage analysis
 - » Identify Routine care vs. Research
 - » Identifies what Sponsor should pay
 - » UTH Research Account
 - » Identifies what subject/subject's insurance should pay
 - » Proper codes and modifiers must be applied for insurance to pay

Study Budget

Internal Budget Development

Internal Charges

Work with internal UTH departments and/or partner hospitals to obtain research pricing

- UTH Pricing
- Memorial Hermann Pricing
- Harris Health Pricing

Study Budget

Internal Budget Development

Time and Effort Assessment

- How much time will it take to perform all of the requirements of the protocol?
 - For Study Coordinator
 - For PI
 - For any additional team members
- Review and assess EACH item of EACH study visit
 - Example: A protocol schedule may require that blood is drawn at each study visit and sent to sponsor's lab for testing
 - How long will it take to complete a venipuncture on the average subject?
 - What about a difficult subject?
 - How long does processing and packaging a specimen take?
 - **Consider both typical and worst-case scenarios**
 - Note some items will require additional effort to complete per protocol
 - Reviewing patient diaries
 - Reviewing medical history since last visit
 - Recording any changes in medications

Study Budget

Internal Budget Development

Effort

When calculating this additional time needed to run the trial, consider the following:

- Communication with the industry sponsor or CRO
- Maintaining study documents (including time to back up critical information)

Creating Source Documentation

Completing case report forms

- Monitoring subject visits
- Faxing or emailing documents, or completing on-line forms
 - Resolving queries
 - Reporting serious adverse events
- Submitting appropriate documentation to the IRB

Study Budget

Internal Budget Development

Additional Costs identified

- Costs not included in per patient
 - SAE reporting
 - Monitoring Visits
 - Processing IND safety reports
 - Protocol Amendments
 - IRB submission
 - SPA submission of contract/budget amendment

Study Budget

Internal Budget Development

Additional Costs identified

- One Time Fees
 - Start up administration costs
 - IRB Review
 - IDS Start up fee
 - Record Retention Fees
 - Radiology Start up fee
 - Coverage Analysis Fee

Study Budget

- Study Budget
 1. Internal Budget Development
 2. **Budget Negotiations with Sponsor**

Study Budget

Budget Negotiations

Budget Negotiation with Industry Sponsors

- The process of engaging the sponsor in a dialogue that results in a final budget that covers the costs of participating in a clinical trial
- During budget negotiations UTH and the sponsor propose and counter-propose line item costs to arrive at a mutually agreeable budget.

Study Budget

Budget Negotiations

As you begin negotiating it is important to be prepared and knowledgeable about the clinical trial. Advanced planning, preparation and patience are key skills in a successful negotiation.

Study Budget

Budget Negotiations

In the case of an industry sponsor-defined budget, the initial proposed amount typically is not adequate to cover costs.

In most cases, a reasonable agreement can be reached

Study Budget

Budget Negotiations

There are some cases in which a PI may need to decline participation in a clinical trial because the budget is inadequate for the work

Financial Considerations

- Study Budget
- **Payment Terms**

Payment Terms

Payment Terms

- Timing
- Hold back
- Final Payment
- invoicing
- IDC

Payment Terms

Timing

Payment Schedule

Monthly? Quarterly? Only after Monitor has approved CRF forms?

Payment Terms

Withholding

- NEVER allow sponsor to hold back more than 10%
- Ensure final payment includes all funds held

Payment Terms

Invoicing

Per subject

- Which items should be invoiced?
- Which items are paid automatically based upon CRF Completion?

Payment Terms

IDC

We should NOT offer waivers of IDC

Payment Terms

Tip

Review final version of
contract

Make sure the final budget and payment terms have been inserted.

Occasionally, in the rush of completing CTA the wrong version gets inserted.

Payment Terms

Not financial but...

- Provisions for Monitoring
- ICH GCP not always needed
 - Many industry funded studies are NOT under IND/IDE
- If remote monitoring will occur
 - Complete paperwork/contracts for institutional authorization for EMR access

Thank you



The University of Texas
Health Science Center at Houston

**Sponsored Projects
Administration**