Industry Sponsored Clinical Trial Agreements

Financial Considerations

UTHealth®
The University of Texas
Health Science Center at Houston

Sponsored Projects
Administration

Financial Considerations

- Study Budget
- Payment Terms

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- **Study Budget**
- Payment Terms

Study Budget

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

Study Budget

- Study Budget
  - **Internal Budget Development**
  - 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

Additional Costs identified

- Costs not included in per patient
  - 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 Fee

Study Budget

- Study Budget
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  - **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

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

Study Budget
Budget Negotiations

Points to remember when negotiating with sponsors:

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Payment Terms

Payment Terms

- Timing
- Holdback
- Invoicing
- Price capping
- Final Payment
- IDC

Payment Terms

Invoicing

- Per subject payments vs. items to be invoiced
- CRF Completion

Payment Terms

Timing

Payment Schedule

Payment Terms

Withholding

- NEVER allow sponsor to hold back more than 10%

Payment Terms

Withholding

- NEVER allow sponsor to hold back more than 10%

Payment Terms

IDC

We should NOT be offering waivers of IDC

Payment Terms

Tip

Review final version

Payment Terms

Not financial but…

- Provisions for Monitoring
- ICH GCP not always needed
  - Many industry funded studies are NOT under IND/IDE

  - Advanced notice
  - Complete paperwork for institutional authorization for EMR access

Additional Time &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

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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.

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