Industry Sponsored Clinical Trial Agreements

Financial Considerations

UTHealth | Sponsored Projects Administration

The University of Texas Health Science Center at Houston
Financial Considerations

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

Additional Costs identified

- Costs not included in per patient
  - Processing IND safety reports
  - Protocol Amendments
    - IRB submission
    - SPA submission of contract/budget amendment
Additional Costs identified

- One Time Fees
  - Start up administration costs
  - IRB Review
  - IDS Start up fee
  - Record Retention Fee
Study Budget

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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.
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.
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.
Points to remember when negotiating with sponsors:
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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%
Withholding

- NEVER allow sponsor to hold back more than 10%
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
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.