Industry Sponsored Clinical Trial Agreements

Financial Considerations



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Study Budget

Payment Terms

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Internal Budget Development

Budget Negotiations with Sponsor

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Budget Negotiations with Sponsor

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

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

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

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 Budget Negotiations with Sponsor

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

Invoicing

Per subject payments vs. items to be invoiced

CRF Completion

Timing

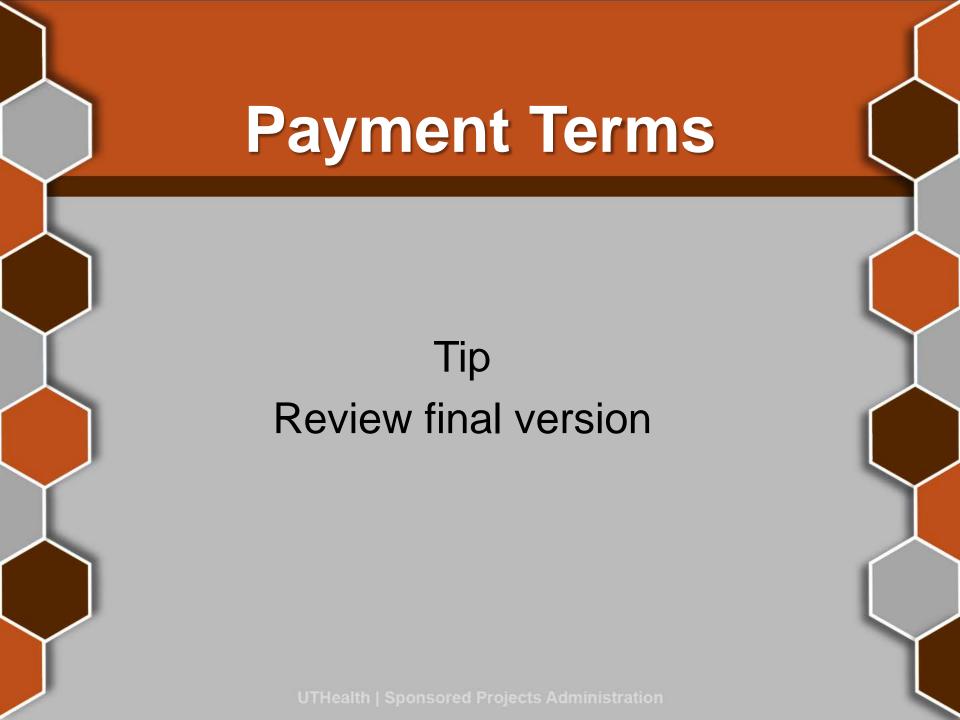
Payment Schedule

Payment Terms Withholding NEVER allow sponsor to hold back more than 10%

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IDC

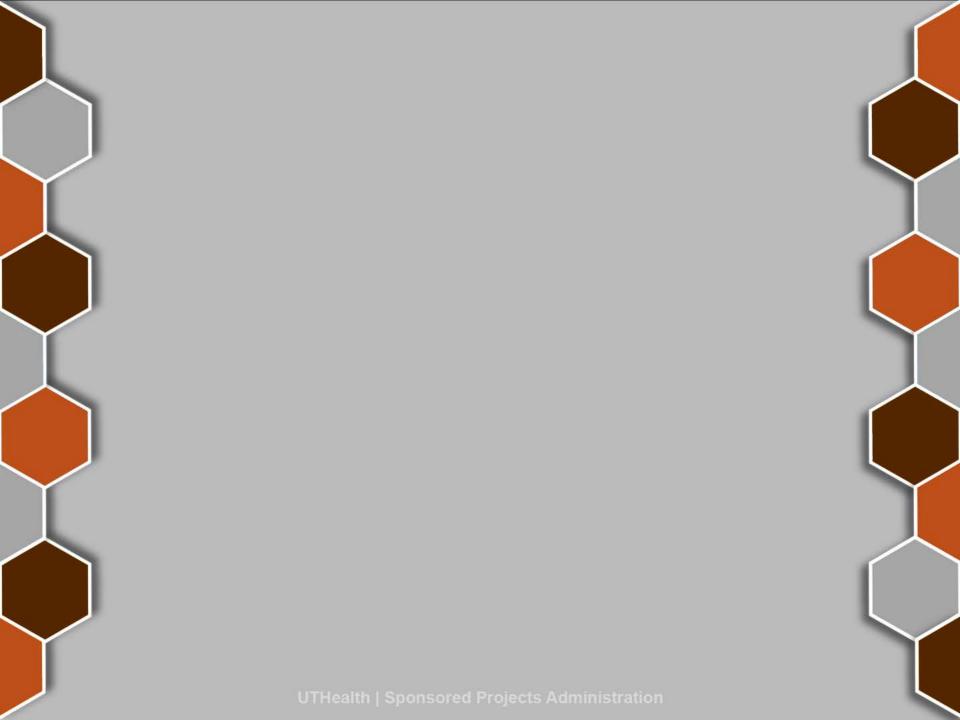
We should NOT be offering waivers of IDC

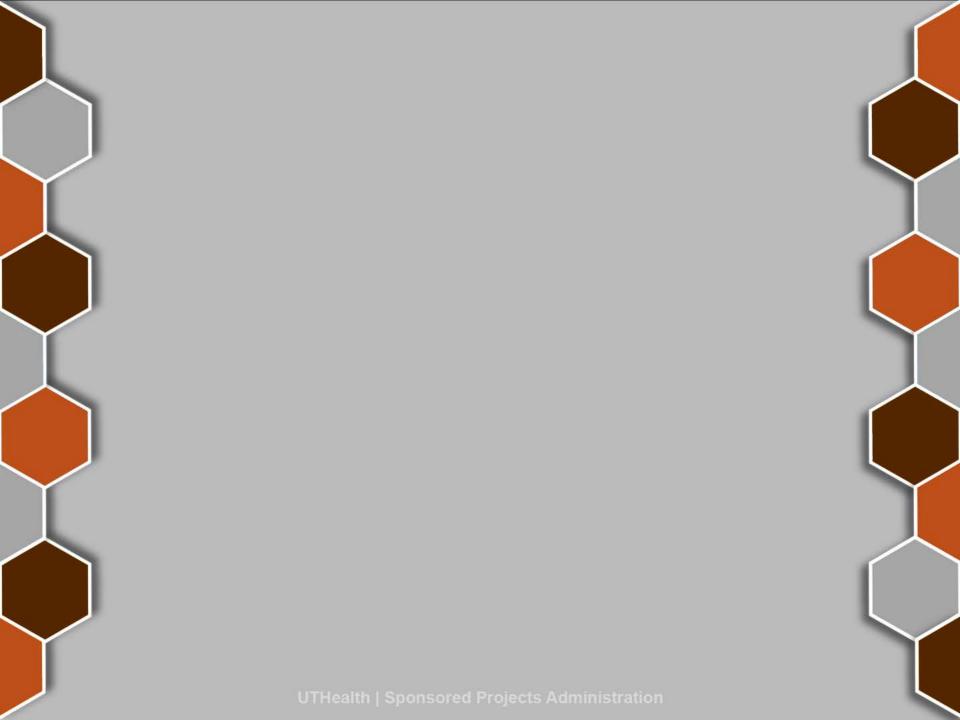


Not financial but...

- 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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