Effective Budgeting and Contract Negotiations for Clinical Trials

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Workshop Objectives

- Examine what is needed for Budget Development
- Learn what to review in the Study Protocol and identify potential hidden costs
- Types of Study Budgets
- Review Payment Schedules and their Implications
- Contract Terms and Helpful Negotiation Strategies
- Group Exercise
Study Budget Development
In Preparing to Develop the Budget

- Obtain final version protocol
- Obtain clarifications from sponsor (i.e., use of central lab, supplied equipment, additional reporting, training, etc)
- Review basis of protocol with Principal Investigator and/or study team
- Assess needs and key components required for the implementation of the protocol
Reviewing the Protocol

- Read the protocol to understand the visits and complexity of the trial
- Determine if there will be other affected areas
- Look at all of the components of the protocol
  - Schedule of events
  - Schema
  - Visit detail
  - Informed consent template
  - Case Report Forms
Reviewing the Protocol:

Laboratory
- Central lab vs local lab
- Who’s drawing the blood
- Who will process the samples
- If local what if a test is positive?

Radiology
- Copies of Films
- Who will read the Films

Cardiology
- Echos
- Reading fees

Pulmonary
- PFTs

Pharmacy
- Tracking
- Randomization
- Preparation
- Drug Dispensing
- Specific requirements for monitoring
- Drug return or destruction at conclusion of trial

Pathology
- Reading Fees
- Additional Slides or Blocks
Developing the Study Budget: Research vs Standard of Care

**Research**
- Non-covered, non-routine charges
- Patients would not generally be receiving this care
- Cost of care is billed to sponsor

**SOC**
- Routine care that the patient would receive regardless of study participation
- Cost of care is billed to third party provider or patient (e.g., “covered” charges)

Review parameters of the contract and the informed consent to assure full disclosure to the participants after determination is made
SOC vs Research: What Does this Mean? What Questions to Ask?

For each item/procedure, ask:

- Why is this being done?
- What is the reason/diagnosis for the service?
- Is the sponsor covering the charges for the procedures?
- Does your institution have regulations/guidelines regarding standard of care? Can you interpret what they say?
Types of Study Budgets

- Flat amount per patient
  - $10,000 per patient including Indirect Costs (IDC)
  - Not Detailed
  - IRB Fees, Advertising, Start-up, Pharmacy, etc

- Payment Per Visit
  - Each Visit has flat fee
  - Not Detailed

- Payment Per Activity
  - $$ amount is attached to each service/procedure associated with the protocol, references schedule of events/procedures to be performed
  - Includes PI and Coordinator fees
  - IDC rate, IRB Fees, Pharmacy, Lab, Nursing, etc
Study Budget Costs

- Start up costs
  - Non-subject charges
  - Standard across Institution

- Per-subject costs
  - Budget for one single, completed subject

- Variable/ Event Based costs
  - Event that may or may not occur during the study
Start Up Costs

- Initial IRB Preparation and Review Fees
- Pharmacy Review Fees
- Lab Review Fee
- Regulatory Document Preparation
- Storage Fee
- Radiology Review Fee
- Administrative Fee
- Advance Upfront Payment
- Start Up Fee
  - PI and Coordinator Effort, Investigator meeting, Site Initiation, etc…
- Other fees applicable to institution
  - Clinical trial fee
## Per Subject Study Costs

### Patient Care
- Procedures
- Tests
- Labs

### Subject Costs
- Stipends
- Travel
- Lodging

### Personnel Costs
- Physician
- Coordinator
- Nursing
- Lab Tech
- Other Specialists
Variable Thru Fees/ Event Based Fees

- Annual IRB Preparation and Review Fee
- Quarterly Pharmacy Fee
- IRB Amendment Preparation and Review Fee
- Safety Report Preparation & Review Fee (exceeds \( x \)) will charge $100 or $30 for each
- Advertising Fee
- Medical Records Fee – copying or pulling records
- Supply Fee
- Additional Training
- IDC and Other Fees applicable to your site
What is the Most Important Cost Element of a Budget?

Personnel Costs
Personnel Costs: Study Coordinator

- Recruitment
- Screening
- Consenting
- Randomization
- Review of diaries
- Pill counting
- Coordinating the study visit-scheduling
- Amount of time at each study visit
- Communication with study participant/family
- Training

- CRF Completion: paper or electronic
- Maintenance of study files and Regulatory binder
- SAE Reporting
- Monitoring Visits
- Communications with monitor and sponsor
- Resolving Queries
- Close out visit
Personnel Costs: Research Nurse

- PK Study – multiple and timed blood draws
- Infusions
- Administration of study drug or device
- IV start and blood drawing
- Vital signs
- Clinical testing that the PI would delegate to the nurse
- Online training
- Investigator Meetings
Personnel Costs: Lab Technologist

- Collection and or storage of samples
- PK Studies
- Processing of samples
- Dry ice / lab supplies / centrifuge
- Shipping materials
- Packaging of samples
  - Labeling and completion of courier forms
  - Who’s paying for shipment?
Personnel Costs: Physician Fees

Physical Exams
• Initial
• Complete
• Limited
• Follow-up

Procedural Charges

PI Fee – Responsible for the conduct of the study

On-line Training

Investigator Meetings
Other Budget Considerations

- Inpatient vs Outpatient
- Potential for multiple Amendments
- Adult vs. Pediatric Trials
- Duration of Study
- Complexity of Study
- Difficulty recruitment of study participants
- Amount of Resources Used
- Special Training required
Study Budget Hidden Costs

- Re-consenting and the cost involved
- Local IRB submission of amendments, IC changes
- Multiple monitoring visits which exceeds standard visits
- Printing costs for electronic medical records, etc
- Teleconference attendance (pre-study and during study)
- Study delays and unscheduled visits
- Completion of CRFs /Electronic CRFs
- Early termination
- Phone call follow up or Long term follow up
Payment Schedules
Payment Schedules: When do you get Paid?

Expectation of Initial Payment

- Invoiced upon executed contract
- Start Up Costs – IRB Fees, Regulatory Fee, Pharmacy, Storage, Administrative Fee, etc.
- Advance Payment for One Patient

“If no subjects are enrolled, Site agrees to refund payment to sponsor after deducting any costs incurred including recruitment efforts, screening log documentation, inserving meeting, etc.”
Payment Schedule

Payments triggered upon CRF completion

- Dependent upon monitoring and frequency of visits
- Submission to data management
- **What if payment is contingent upon queries being answered?**

Payments triggered upon number of patients enrolled

- After first patient enrolled? After first 5 patients, then 10, etc.
- **What happens if no patients are enrolled?**
- **What happens if only 1 to 4 patients are enrolled?**

Payment triggered upon number of completed visits

- Payments received in a reasonable time
- Study doesn’t run in a deficit
Payment Considerations: Invoicing and Holdbacks

- IRB Fees - Limiting # of amendments and annual approvals

- Safety Reports - Caps are placed on how many or how payment is made, i.e., one lump sum

- Screen Failures - Paid by a flat fee and not based upon costs incurred per screening visit and language limits the number of screen failures

- Early Termination of Subject - Payment for subject made at the end of the study rather than upon month or quarter of termination

- % of Payment withheld

- Final Payment - When and how is it triggered
Approaches to Contract Negotiations
Are You Prepared to Negotiate?
Roles and Responsibilities

- Who Negotiates?
  Contract Officer, Administrator, Legal Office, PI, ...

- Who’s Involved?
  PI, Manager, Coordinator, Department Administrator, ...

- What are the level of approvals?
  Legal, Department Head, CFO, VP, PI, ...
Preparing to Negotiate: Planning Strategies

Planning is Critical!

Review, Review and Review

Justification!

- Identify potential issues
- Be prepared to justify
- Know the importance of the issues of what you are negotiating
- Know what are must have items, what items you want to have and what you are able to concede
Negotiation Strategies

Set the Tone

- Be fair and communicate clearly
- Listen to the concerns
- Always remain courteous
- Be firm when you need to be and give a little when able
- Give and take is a good mutual feeling for both parties

Always summarize the agreement

Don’t be afraid to say no Sometimes you just can’t agree!
Clinical Trial Agreements: Key Sections to Review
Clinical Trial Agreements: Important Sections to Review

- Budget and Payment Schedule
- Termination Clause
- Monitoring or Auditing Visits
- Case Report From Completion
- Publication
- Subject Injury
Clinical Trial Agreements: Subject Injury

Compare the Informed Consent and the Clinical Trial Agreement!

Do they match?

Who is paying for what and to whom?

Do you have an Institutional Template?

Is your institution AAHRPP Accredited?
Clinical Trial Agreements
Contract Terms – Subject Injury

ICF Research Injury: If you are injured as a direct result of participating in this study, any immediate, short-term medical treatment related to this injury is available at Hopeful University. You will be reimbursed by the sponsor, for reasonable medical expenses that are needed for treatment of the injury. Sponsor will not compensate you where such injury results from any other procedure carried out which is not according to the study protocol, and no other compensation is offered.

CTA Research Injury. For purposes of this indemnification and research injury policy, the term “Research Injury” means physical injury caused by treatment or procedures required by the Protocol that the Study subject would not have received if the subject had not participated in the Study. Institution agrees to provide or arrange for prompt diagnosis and medical treatment of any Research Injury experienced by a Study subject. Institution further agrees to promptly notify Sponsor of any Research Injury.
### Connecticut Children's Medical Center

**Sponsored Research Clinical Trial Agreement Checklist**  
(To be completed with review of each funding agreement involving research with human subjects at CCMC)

**Title of Study:**  
**Name of CCMC Principal Investigator:**  
**Name of Sponsor:**  
**Checklist completed by:**  
**Date:**  

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<thead>
<tr>
<th>ITEM</th>
<th>Indicate status</th>
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<tbody>
<tr>
<td>Written agreement specifies that CCMC will conduct the research in accordance with the protocol, applicable law, and CCMC IRB/P.</td>
<td></td>
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<tr>
<td>Written agreement/consent specifies who provides medical care for research related injuries?</td>
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<tr>
<td>Written agreement and consent addresses who pays for medical care for research related injuries?</td>
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<tr>
<td>Written agreement and consent form agree?</td>
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<tr>
<td>If sponsor bears responsibility for monitoring the research, written agreement requires Sponsor to promptly report to CCMC findings that could affect the safety of participants; affect their willingness to continue participation; influence the conduct of the study; or alter the IRB's approval to continue the study?</td>
<td></td>
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<tr>
<td>For example: “Sponsor will report to CCMC promptly any findings that could affect the safety of participants or their willingness to continue participation, influence the conduct of the study, or alter the IRB's approval to continue the study.”</td>
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<tr>
<td>Written agreement will specify publication procedures that are consistent with CCMC publication guidelines.</td>
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<tr>
<td>Written agreement specifies steps to be followed to communicate results from a research study to current or past participants, when those results directly affect their safety or medical care:</td>
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<tr>
<td>• Specifies Sponsor's responsibility to notify CCMC?</td>
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<tr>
<td>o For example: “When the safety or medical care of current or past participants could be directly affected by study results, Sponsor will promptly notify CCMC and investigator.”</td>
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<td>• Specifies CCMC's responsibility to notify participants?</td>
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<td>o For example: “When the safety or medical care of current or past participants could be directly affected by study results, as reported by Sponsor, CCMC will use its best efforts to communicate that information to study participants in a letter approved by the IRB.”</td>
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<td>Written agreement includes language consistent with CCMC performance for early termination if notice not requiring breach of contact.</td>
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g:/drive/clinical trials/lsastudyfiles/contracts
Negotiation Exercise
Conclusion/Summary

- There are a multitude of expenses and costs to considered and included in study site budgets.
- Know your costs and identify hidden costs
- Payment terms are essential for cash flow
- The negotiation process should be fair and honest
Questions