Study Budgets: Industry Sponsored Studies

Kelsey Richey
Center for Clinical Research (CCR)
Learning Objectives

• Identify the components of a clinical trial budget
• Identify hidden costs
Topic Overview

• Budget Development Basics
• Components of a Clinical Trial Budget
  - Subject Costs
  - Non-Subject Fees/ Admin. Fees/ Contingent Fees
• Useful Tips
Budget Development Basics

Documents Needed

• What you need:
  - The sponsors budget template
  - Contract
  - Protocol
    • Schedule of Assessments
  - Informed Consent
  - May need:
    • Imaging Manual
    • Laboratory Manual
    • Pharmacy Manual
## Budget Development Basics

### Example Internal Budget

### Center for Clinical Research (CCR) Financial Services Program

#### Investigator:

*Draft Budget*

#### Sponsor:

- NUCACT Study #
- SPAR

#### Chart title:

<table>
<thead>
<tr>
<th>Event</th>
<th>Screening</th>
<th>Baseline</th>
<th>D1</th>
<th>D7</th>
<th>D14</th>
<th>M24</th>
<th>M27</th>
<th>EOS</th>
<th>EOT</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
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<td>5</td>
<td>14</td>
<td>15</td>
<td>16</td>
<td></td>
</tr>
</tbody>
</table>

**Coordinator:**

- Coordinator
- Time/Effort
- PI (& Sub-I) Time/Effort
- Labs
- NMHC (Hospital Fees)
- NMG (Professional Fees)
- Subject Stipend
- Pharmacy
- Overhead

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**Coordinator Time/Effort**

<table>
<thead>
<tr>
<th>Coordinator:</th>
<th>Time/Effort</th>
<th>PI (&amp; Sub-I) Time/Effort</th>
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<tbody>
<tr>
<td></td>
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**Labs**

<table>
<thead>
<tr>
<th>Labs</th>
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</thead>
<tbody>
<tr>
<td></td>
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**NMHC (Hospital Fees)**

<table>
<thead>
<tr>
<th>NMHC</th>
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</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

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**NMG (Professional Fees)**

<table>
<thead>
<tr>
<th>NMG</th>
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<tbody>
<tr>
<td></td>
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**Subject Stipend**

<table>
<thead>
<tr>
<th>Subject Stipend</th>
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<tr>
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**Pharmacy**

<table>
<thead>
<tr>
<th>Pharmacy</th>
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<tr>
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</table>

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**Overhead**

<table>
<thead>
<tr>
<th>Overhead</th>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
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**Total per patient per visit**

<table>
<thead>
<tr>
<th>Event</th>
<th>Screening</th>
<th>Baseline</th>
<th>D1</th>
<th>D7</th>
<th>D14</th>
<th>M24</th>
<th>M27</th>
<th>EOS</th>
<th>EOT</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$36,641.55</td>
<td>$36,641.55</td>
<td>$27,807</td>
<td>$27,807</td>
<td>$27,807</td>
<td>$27,807</td>
<td>$27,807</td>
<td>$27,807</td>
<td>$27,807</td>
</tr>
</tbody>
</table>

**38,169.93$**

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**Estimated Number of Subjects:**

*1*

**Total Subject Budget (if all 1 subjects are enrolled and remain in the study for the life of the study):**

*49,620.91$*

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**Sponsors Budget Offer/Amount in Contract**

<table>
<thead>
<tr>
<th>Event</th>
<th>Screening</th>
<th>Baseline</th>
<th>D1</th>
<th>D7</th>
<th>D14</th>
<th>M24</th>
<th>M27</th>
<th>EOS</th>
<th>EOT</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$3,888.29</td>
<td>$3,888.29</td>
<td>$2,222.22</td>
<td>$2,222.22</td>
<td>$2,222.22</td>
<td>$2,222.22</td>
<td>$2,222.22</td>
<td>$2,222.22</td>
<td>$2,222.22</td>
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</tbody>
</table>

**2,531.82$**

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**3,031.82$**

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**Draft Budget**

*7-Jul-2016*
### Budget Development Basics

*(Every Sponsor will have a different template)*

#### Procedures

<table>
<thead>
<tr>
<th></th>
<th>Total Quantity</th>
<th>Total Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Informed Consent</td>
<td>1.00</td>
<td>150.00</td>
</tr>
<tr>
<td>Complete Physical (Med Hx, Height)</td>
<td>1.00</td>
<td>215.00</td>
</tr>
<tr>
<td>Comp. Follow-Up Visit w/Phys/Visits</td>
<td>1.00</td>
<td>180.00</td>
</tr>
<tr>
<td>Vital Signs</td>
<td>13.00</td>
<td>25.00</td>
</tr>
<tr>
<td>ECG</td>
<td>3.00</td>
<td>125.00</td>
</tr>
<tr>
<td>Review Concomitant Medications</td>
<td>16.00</td>
<td>35.00</td>
</tr>
<tr>
<td>Intranasal Injection of REGN2176-3 Or</td>
<td>13.00</td>
<td>400.00</td>
</tr>
<tr>
<td>BCVA</td>
<td>16.00</td>
<td>90.00</td>
</tr>
<tr>
<td>Fluorescein Angiography</td>
<td>4.00</td>
<td>300.00</td>
</tr>
<tr>
<td>Fundus Photography</td>
<td>4.00</td>
<td>115.00</td>
</tr>
<tr>
<td>SD-OCT</td>
<td>16.00</td>
<td>110.00</td>
</tr>
<tr>
<td>Ocular Blood Flow by Repetitive IOP</td>
<td>28.00</td>
<td>88.00</td>
</tr>
<tr>
<td>Indirect Ophthalmoscopy</td>
<td>28.00</td>
<td>90.00</td>
</tr>
<tr>
<td>Slit Lamp</td>
<td>15.00</td>
<td>100.00</td>
</tr>
<tr>
<td>Venipuncture/Sample Handling</td>
<td>12.00</td>
<td>25.00</td>
</tr>
<tr>
<td>Urinalysis</td>
<td>5.00</td>
<td>30.00</td>
</tr>
<tr>
<td>Adverse Events Assessment</td>
<td>16.00</td>
<td>50.00</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Per Patient Procedure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overhead at 30.50%</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Per Patient Procedure Subtotal</td>
<td>1,973.40</td>
<td>1,541.80</td>
</tr>
</tbody>
</table>

#### Other Direct Costs

<table>
<thead>
<tr>
<th></th>
<th>Total Quantity</th>
<th>Total Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physician’s Fees without Exam Costs</td>
<td>16.00</td>
<td>130.00</td>
</tr>
<tr>
<td>Salaries: Coord, Nurse, Admin, Tech</td>
<td>16.00</td>
<td>165.00</td>
</tr>
<tr>
<td>Pharmacy Dispensing</td>
<td>13.00</td>
<td>20.00</td>
</tr>
<tr>
<td>Patient Daily Reimbursement</td>
<td>16.00</td>
<td>50.00</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Per Patient Other Direct Cost</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overhead at 30.50%</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Per Patient Other Direct Cost Subtotal</td>
<td>448.50</td>
<td>474.50</td>
</tr>
</tbody>
</table>

#### Cost Per Patient Totals

| Total Cost | 2,421.90 |

### Invoice Items

<table>
<thead>
<tr>
<th>Name</th>
<th>Total Quantity</th>
<th>Total Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Archiving/Document storage/per site</td>
<td>1.00</td>
<td>650.00</td>
</tr>
<tr>
<td>Closeout Fee</td>
<td>1.00</td>
<td>1,000.00</td>
</tr>
<tr>
<td>Initial Rb Fee</td>
<td>1.00</td>
<td>5,000.00</td>
</tr>
<tr>
<td>Rb renewal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rb Amendment</td>
<td>1.00</td>
<td>750.00</td>
</tr>
<tr>
<td>Site Start-up Costs</td>
<td>1.00</td>
<td>5,000.00</td>
</tr>
<tr>
<td>Initial Pharmacy Fee</td>
<td>1.00</td>
<td>3,900.00</td>
</tr>
<tr>
<td>Annual Pharmacy Fee</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SAE report prep fee</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Screen Failure</td>
<td>1.00</td>
<td>2,421.90</td>
</tr>
<tr>
<td>Serum Pregnancy Test, Quantitative</td>
<td>2.00</td>
<td>39.00</td>
</tr>
<tr>
<td>Urine Pregnancy Test, Qualitative</td>
<td>13.00</td>
<td>250.00</td>
</tr>
</tbody>
</table>
Budget Development Process

1. Read the protocol including footnotes in Schedule of Assessments
2. Review the sponsors budget grid and payment terms
3. Developing the internal study budget – Accounting for all costs
4. Revise sponsors template based on the internal budget
5. Justify costs
Industry Sponsored Budget Components

Non-Subject Fees/ Admin. Fees/ Contingent Fees (need to be invoiced)

Subject Costs (may or may not need to be invoiced)
Subject Costs

Determining Standard of Care is the First Step in Developing the subject budget

- Determining research costs vs. standard of care (SOC)
  - PI should be determining what costs are SOC (not the sponsor)
    - If the PI would not typically order the procedure for a clinic patient (with the same condition) then it would not qualify as SOC for the research subject.
  - Easiest method: Provide the schedule of assessments to PI and have the PI highlight the items that are SOC
  - Verify what the SOC frequency is
    - The item may be SOC every 6 weeks but the study calls for the item every 3 weeks
      - If insurance won’t cover the frequency needed, you need to negotiate with the sponsor to ensure the sponsor will pay for what the insurance won’t
Industry Sponsored Budget Components

- Per Subject budget (Subject visits)
- Invoiced Subject Costs
- Subject Costs
Subject Costs
Per Subject Budget

Staff Costs
(PI and coordinator)

Procedures
(NMHC & NMG)

Labs

Pharmacy (Dispensing)

Subject Payments
(Stipends)

Overhead

Per Subject Budget

Invoiced Subject Costs
Per Subject Budget

Coordinator Costs

• Estimating Coordinator Time
  - Protocol Required Activities
    • Informed Consent (estimated 3 hours)
    • Inclusion/Exclusion Criteria & Medical History
    • Questionnaires
    • Assessments
  - Additional time waiting for subject
  - eCRFs (electronic case report forms)
    • Estimated that for every 1 hour spent with subject there is 1.5 hours of paperwork
  - Subject Recruitment & Pre-screening
  - Scheduling
  - Regulatory Paperwork
  - Monitor Visits
    • What is the monitoring visit schedule
    • Remote monitoring still takes staff time
  - Estimated number of subjects

• Remember: It always takes longer than you expect
Per Subject Budget

Coordinator Costs

• Options for accounting for coordinator time in budget
  - Percent Effort
  - Estimated number of hours per visit
    • Be sure to include administrative time for the coordinator
    • Estimated: For every 1 hour spent with a subject the coordinator will spend approx. 1.5 hours on paperwork
  - Assigning dollar amounts to activities/assessments
Per Subject Budget
Coordinator Costs – Percent Effort

• Percent Effort must be allocated to visits and number of subjects
• Percent Effort Calculation
  - \( \frac{(\text{Salary} + \text{Benefits}) \times \% \text{ effort}}{\text{# of anticipated subjects}} \)
    • This formula calculates the amount that needs to be included per subject.
    • The amount calculated is then allocated across the visits.
• Be realistic on the number of anticipated subjects
  - If you base the calculation on more subjects then are actually enrolled then the study will likely end in a loss.
Per Subject Budget

Physician Costs

- Estimating PI Time
  - Physician Oversight
    - Review of Labs
    - Review of SAE’s
  - Exams
    - Physical Exams – Different for every department
      - Does the study include a full exam on some visits and a partial exam on other visits?
      - Physical Exam costs (99201-99205, 99211-99215)
      - There are different rates for the first visit (new Subjects) and established Subjects
  - Percent Effort
    - Be realistic on the percent effort
  - Assigning dollar amounts to activities/assessments
Per Subject Budget

Procedure Costs (NMHC and NMG)

• CPT (Current Procedural Terminology) codes needed for NMHC and NMG procedures
  - Account for both the technical fee and the professional fee

• Radiology
  - Does the CPT code include all of the images the protocol requires?

• Is a case rate needed?
  - Is the subject admitted?
  - Contact NMHC Office of Research

• Be sure to use the current research chargemaster (updated each fiscal year)
Per Subject Budget

Labs

• Central Lab
  - Who will be processing/shipping the samples?
  - Include estimated staff time to collect/process/ship samples

• Local Lab
  - Prices in NM research price catalog
    • CPT code for tests is needed
  - The protocol may list a panel such as chemistry or hematology
    • This DOES NOT mean that it is the same as the panel at the site
    • Verify in the protocol what the sponsor is including in the panel and compare to the labs included in the NMHC panel

• Always include Phlebotomy fee for studies that have blood draws
Per Subject Budget

Subject Stipend – Travel Reimbursement

• Is there a subject stipend? How much is the stipend?
  - Is the amount coercive?
  - Confirm the amount in the budget matches the informed consent
    • The amount in the budget needs to include the 30% overhead.
    • If you see an amount in the budget of $65 (inclusive of overhead) that DOES match the consent because it is $50 that the subject is receiving

• Is the sponsor directly paying the subject?
  - Gift cards provided by sponsor
    • Stipend amount does not need to be included in the subject

• Is the site processing the payment?
  - If so then the indirect cost rate needs to be applied to the stipend

• Can be used to cover:
  - Parking
  - Time
  - Meals

• Extra stipend for long visits
  - Example: Timed PK draws

• Extra stipend for visits with additional procedures
  - Example: MRI’s

• Travel and stipend payments are subject to IRB approval
  - Must be included in the informed consent
  - Should not be coercive
Per Subject Budget

Pharmacy

• Are you utilizing the investigational pharmacy?
  - There are costs for EVERY time the drug is dispensed by the pharmacy
  - Even if you are not using the pharmacy to store the drug there are still costs

• If the department/coordinator is storing the drug
  - Include time for the coordinator to dispense drug
  - Include time for the coordinator if they have to account for the Subjects compliance such as collecting the bottles and counting the # of missed doses

• At the time of budget development the pharmacy manual is typically not available. To determine the actual dispensing amount for injectables contact the pharmacy.
Per Subject Budget

Overhead

• Overhead is applied to ALL items in any Industry Sponsored Budgets
  - NON-NEGOTIABLE
  - IRB fees are the only fees that DO NOT have indirects applied.
• Double check advertising, subject stipends, and invoiced items to ensure the sponsor will pay the overhead
  - Many sponsors consider these “flow-through” items
Subject Costs

Screen Failures

• Is sponsor only paying for procedures performed (prior to subject being deemed a screen failure)?
  - Make sure staff time is included in the amount you will be paid
• Is sponsor paying the full cost of the screen failure?
  - Ex: Sponsor will pay 80% of the screening visit for screen failures
• Is there a ratio?
  - Ex: for every 3 patients randomized sponsor will reimburse 1 screen failure
• Is there a cap on screen failures?
Industry Sponsored Budget Components

Non-Subject Fees/ Admin. Fees/ Contingent Fees (need to be invoiced)

Budget Components

Subject Costs (may or may not need to be invoiced)
## Non-Subject Fees/ Admin. Fees/ Contingent Fees

### Initial Fees

<table>
<thead>
<tr>
<th></th>
<th>(exclusive of indirects)</th>
<th>(inclusive of indirects)</th>
<th>Comments</th>
<th>Documentation to provide to Sponsor</th>
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</thead>
<tbody>
<tr>
<td><strong>IRB Fees</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Initial IRB Review</td>
<td>$2,500.00</td>
<td>No indirects</td>
<td>Non-negotiable. Charged even if central IRB is being utilized</td>
<td><a href="https://irb.northwestern.edu/about/fees">https://irb.northwestern.edu/about/fees</a></td>
</tr>
<tr>
<td>IRB Annual Renewal/Closeout (each)</td>
<td>$750.00</td>
<td>No indirects</td>
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<td></td>
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<tr>
<td><strong>Pharmacy Fees</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacy Startup Fee</td>
<td>$3,000.00</td>
<td>$3,900.00</td>
<td>If your study has investigational product the pharmacy fee should be included in the budget and non-negotiable. Have the sponsor complete the pharmacy worksheet.</td>
<td></td>
</tr>
<tr>
<td>Pharmacy Annual Maintenance (low)</td>
<td>$300.00</td>
<td>$390.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacy Annual Maintenance (med.)</td>
<td>$700.00</td>
<td>$910.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacy Annual Maintenance (high)</td>
<td>$1,000.00</td>
<td>$1,300.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Study Initiation Fee (Total $10,725)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Initial Regulatory Preparation and Submission</td>
<td>$3,250.00</td>
<td>$4,225.00</td>
<td>Covers the staff time associated with preparation/submission of IRB and regulatory documents</td>
<td><a href="#">CCR Memo (dated Sept. 19, 2016): FY 2017 Research Fees: One time fees for Industry Sponsored Research</a></td>
</tr>
<tr>
<td>Coordinator Startup</td>
<td>$1,000-$3,000</td>
<td>$1,300-$3,900</td>
<td>Covers the coordinator time associated with getting the study open. Amount depends on what sponsor requires from coordinator.</td>
<td></td>
</tr>
<tr>
<td>Admin Startup</td>
<td>$2,000.00</td>
<td>$2,600.00</td>
<td>Covers the staff time associated with budget development and negotiation</td>
<td></td>
</tr>
</tbody>
</table>
Non-Subject Fees/ Admin. Fees/ Contingent Fees

Study Initiation Fee/Start-up Fee

The study initiation fee is $10,725 (inclusive of indirects) and covers the costs associated with the many processes and department services required for site initiation at Northwestern.

<table>
<thead>
<tr>
<th>Process</th>
<th>What’s included</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulatory</td>
<td>Interface with Study Team, Sponsor, CRO, and IRB of record; Manage IRB submission including follow-up comments and/or questions arising during approval process; Complete all FDA &amp; Sponsor-required documents (i.e., 1572s, FDFs, CVs, CAP/CLIA); Create and maintain regulatory binder.</td>
</tr>
<tr>
<td>Financial</td>
<td>Coordinate charges between all procedural departments; Gather budget costs and finalize an approved negotiated budget; Handle contract paperwork; Open all study financial accounts.</td>
</tr>
<tr>
<td>Study Coordination</td>
<td>Attend all required protocol training and investigator meetings; Coordinate with various departments for study procedures; Prepare source documents; Organize the site initiation visit.</td>
</tr>
<tr>
<td>Administrative</td>
<td>Miscellaneous management, clerical, and administrative work needed to open the study.</td>
</tr>
</tbody>
</table>
Non-Subject Fees/ Admin. Fees/ Contingent Fees

Coordinator Startup Fee

- The High Complexity ($3,000 exclusive of indirecs) is factored into the Study Initiation Fee. The Study Initiation Fee can be lowered if the coordinator start-up is in one of the lower complexity levels.

- For a copy of the CCR coordinator startup fee questionnaire contact rena.carrizoza@northwestern.edu

<table>
<thead>
<tr>
<th>Type of Study</th>
<th>(points)</th>
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</thead>
<tbody>
<tr>
<td>Phase I</td>
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</tr>
<tr>
<td>Phase II</td>
<td>(4 points)</td>
</tr>
<tr>
<td>Phase III</td>
<td>(3 points)</td>
</tr>
<tr>
<td>Phase IV</td>
<td>(2 points)</td>
</tr>
<tr>
<td>Device</td>
<td>(1 point )</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Typical Start-Up Activities</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Protocol Review</td>
<td>8 hours</td>
</tr>
<tr>
<td>Site Qualification Visit</td>
<td>2 hours</td>
</tr>
<tr>
<td>Site Qualification Visit</td>
<td>4 hours</td>
</tr>
<tr>
<td>Virtual Investigator Meeting</td>
<td>1 hour</td>
</tr>
<tr>
<td>Investigator Meeting</td>
<td>8 hours</td>
</tr>
<tr>
<td>Investigator Meeting</td>
<td>15 hours (≈2 days)</td>
</tr>
<tr>
<td>Site Initiation Visit</td>
<td>4 hours</td>
</tr>
<tr>
<td>Site Initiation Visit</td>
<td>6 hours</td>
</tr>
<tr>
<td>Site Initiation Visit w/certification or training</td>
<td>8 hours</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Additional Start-Up Activities</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Equipment Provided by Sponsor</td>
<td>2 hours</td>
</tr>
<tr>
<td>CRU</td>
<td></td>
</tr>
<tr>
<td>CRU Orders</td>
<td>4 hours</td>
</tr>
<tr>
<td>Coordinating with CRU Core Lab</td>
<td>1 hour</td>
</tr>
<tr>
<td>Coordinating with Diagnostic Testing Center</td>
<td>1 hour</td>
</tr>
<tr>
<td>DEXA/Olsen MRI Training</td>
<td>3 hours</td>
</tr>
<tr>
<td>Lurie Childrens or RIC (if needed)</td>
<td>4 hours</td>
</tr>
</tbody>
</table>

Total Points (add points from above):

Start-up Level Complexity Scale:

- Low Complexity: 1-14 points $1,000.00
- Medium Complexity: 15-28 points $2,000.00
- High Complexity: 29-42 points $3,000.00
## Non-Subject Fees/ Admin. Fees/ Contingent Fees

### Close-out Fees

<table>
<thead>
<tr>
<th>Service Description</th>
<th>Exclusive of Indirects</th>
<th>Inclusive of Indirects</th>
<th>Comments</th>
<th>Documentation to provide to Sponsor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Document Storage (up to 6 years)</td>
<td>$1,000.00</td>
<td>$1,300.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Document Storage (up to 12 years)</td>
<td>$1,500.00</td>
<td>$1,950.00</td>
<td>Review the CTA to find out how long the sponsor is requiring the study documents be stored.</td>
<td>If no documentation available provide sponsor with a signed memo from the PI or chair</td>
</tr>
<tr>
<td>Document Storage (up to 18 years)</td>
<td>$2,000.00</td>
<td>$2,600.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Document Storage (up to 24 years)</td>
<td>$2,500.00</td>
<td>$3,250.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Document Storage (over 24 years)</td>
<td>$3,000.00</td>
<td>$3,900.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study Close out</td>
<td>$1,000.00</td>
<td>$1,300.00</td>
<td>Covers the coordinator time associated with closing out the study (closeout visit, clearing data queries, etc.)</td>
<td>CCR Memo (dated Sept. 19, 2016): FY 2017 Research Fees: One time fees for Industry Sponsored Research</td>
</tr>
</tbody>
</table>

Documentation to provide to Sponsor:
- If no documentation available provide sponsor with a signed memo from the PI or chair.
## Non-Subject Fees/ Admin. Fees/ Contingent Fees

### Maintenance Fees

<table>
<thead>
<tr>
<th>Service</th>
<th>(exclusive of indirects)</th>
<th>(inclusive of indirects)</th>
<th>Comments</th>
<th>Documentation to provide to Sponsor</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRB Annual Renewal/Closeout Prep Fee (each)</td>
<td>$600.00</td>
<td>$780.00</td>
<td>Invoice per occurrence</td>
<td>If no documentation available provide sponsor with a signed memo from the PI or chair</td>
</tr>
<tr>
<td>Protocol Amendments/Preparation Fee (each)</td>
<td>$500.00</td>
<td>$650.00</td>
<td>Invoice per occurrence</td>
<td></td>
</tr>
<tr>
<td>or</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Annual Maintenance Fee ($1,000 Regulatory; $500-1,500 Financial/Admin.)</td>
<td>$2,500.00</td>
<td>$3,250.00</td>
<td>Invoiced annually at time of IRB renewal</td>
<td>CCR Memo (dated Sept. 19, 2016): FY 2017 Research Fees: One time fees for Industry Sponsored Research</td>
</tr>
</tbody>
</table>
The annual maintenance fee is $3,250 and is charged at the time of IRB renewal. This fee covers the costs associated with study maintenance to ensure regulatory compliance including regulatory submissions for IRB periodic reviews and amendments, budget and contract amendments, and financial management of the study account.

<table>
<thead>
<tr>
<th>Process</th>
<th>What’s included</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulatory</td>
<td>Protocol Amendments; Modifications to study documents including consent forms, IBs, recruitment materials; Personnel modifications; Continuing review/study closeout; Regulatory binder maintenance; Interface with study monitors, CRO, sponsor, and IRB; FDA document maintenance (1572, FDFs, CVs, etc.); Support for ClinicalTrials.gov.</td>
</tr>
<tr>
<td>Financial</td>
<td>Invoice; Track patient visits; Reconcile payments received; Provide updates on study account status and accounts receivables; Process subject stipends and NM invoices for payment; Assure billing compliance; Negotiate budget amendments (if needed).</td>
</tr>
</tbody>
</table>
Non-Subject Fees/ Admin. Fees/ Contingent Fees

Recruitment – Hidden Cost

• Recruitment activities extend beyond direct advertising
  - Database maintenance and searching
  - Telephone pre-screening
  - Preparation and placement of recruitment materials
  - Follow-up on subject referrals and chart reviews
  - Scheduling screening visits

• Recruitment is often an unpaid cost
  - Negotiate to offset some of the cost of material development, non-advertising recruitment activity and telephone pre-screening, particularly if site has dedicated recruitment staff
  - Request hourly reimbursement for prescreening to cover some of the prescreening efforts
Non-Subject Fees/ Admin. Fees/ Contingent Fees

Advertising

- Advertising is Expensive
  - Try to get as much as you can
- Add overhead
- Only invoice if advertising actually occurred
- If a site’s advertising strategy has been successful, the sponsor may be willing to approve additional funds for advertising
Budget Development

Justify Costs

• Most sponsors require documentation/justification of costs.
  - Links to documented rates/policies
    • IRB Fees
    • F&A rates
  - Memos (on letterhead)
  - Signed Letters (on letterhead)
  - Pharmacy Worksheet
As a non-profit institution, NU must recover the full cost of research conducted for outside sponsors, including all associated operating costs (overhead). To do otherwise would result in subsidizing for-profit research and could jeopardize the institution's non-profit status.
Budget Development

Fair Market Value

• “Payments for research services should be fair market value for legitimate, reasonable, and necessary services.” (HHS OIG, 2003 Notices) Promoting Objectivity in Research (CFR, Title 42)

• Definition:

  “The fair market value is the price at which the property would change hands between a willing buyer and a willing seller, neither being under any compulsion to buy or to sell and both having reasonable knowledge of relevant facts.” (CFR, Title 26)
Budget Development

Important things to look for in the payment terms

Every contract will be different – with different terms – read the payment terms carefully

- Payment Terms and Frequency
  - When will the sponsor make per Subject payments?
    - Quarterly?
    - After monitoring visits?
  - What triggers the payments?
    - eCRF completion?
    - Monitoring visits?
    - Invoice

- Startup Fee
  - Does the original contract the sponsor sent state that ALL or a percent of the startup fee is refundable?
  - Does the original contract state when the startup fee will be paid?

- Invoiced Items
  - What is the time frame for submitting invoices.

- Screen Failures

- Holdback
Useful Tips

Budget Development

• Read the Protocol to determine expenses
  - DO NOT just create the budget from the study calendar (or the sponsors budget draft).
    • Read through protocol text to ensure it matches the calendar.
  - Not all cost items are included in the schedule of assessments

• Be flexible (if you can)
  - Sponsor may not be willing to add a fee that is titled a certain way but they may be willing to offer something else that would cover the fee.

• Determine what the sponsor is willing to pay

ALL RESEARCH COSTS MUST BE COVERED!!!
Useful Tips

Budget Development

• ALWAYS read the footnotes of the schedule of events
• Beware of lab panels
  - If schedule of assessments or budget lists a lab panel check the protocol to see what tests the protocol is included in the panel
  - Example: Comprehensive Chemistry Panel includes 14 tests, sponsors often include additional tests which will need to be accounted
• Startup Fees should be non-refundable
• Allow room for negotiation
• Be flexible
• Track the holdback so that you know what is due at termination
• ALWAYS double check the formulas in the spreadsheet to ensure ACCURACY
  - Make sure totals are correct

Hints & Tips
Potential Causes for Delays

Items necessary before CTA can be signed

- **IRB Approval**
  - OSR needs copies of the IRB approval letter and the approved ICF

- **COI clearance**
  - Every study is reviewed for possible conflicts of interest
    - If there is a potential conflict the study may need to be reviewed at the monthly COI meeting
    - May require a change of PI if there is a conflict of interest

- **Device Committee Approval (If device study)**
  - Every investigational device must be submitted to the device committee and the committee will determine if a presentation at their monthly meeting is required

- **All approvals obtained on the InfoEd proposal**
  - PI and dept. chair must approve the InfoEd proposal
It is EXTREMELY important to review the details of the protocol and payment terms because once you have agreed to a budget and the contract is signed it is VERY difficult to get the sponsor to revise the budget.

Double-Triple check your budget before sending to sponsor
Review of Learning Objectives

- Identify the components of a clinical trial budget
- Identify hidden costs