# An Introduction to Industry Clinical Trial Budget and Contract Negotiation

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# Objectives

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To understand responsibilities in budget and contract negotiation

To provide an overview of the process of reviewing and negotiating a study budget

To provide basic strategies in successfully negotiating study budgets, and understand the importance of careful review of payment terms

To identify common budgetary pitfalls and concerns

# Outline

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- Overview of the Industry Clinical Trial Agreement (CTA) Process
  - Review roles and responsibilities of budget and contract negotiation
- Industry Funding Overview
  - Understand how items are paid (per patient enrolled, per invoice, etc.)
  - Internal budget vs. external budget
- Reviewing and Negotiating a Study Budget
  - Determining anticipated costs of the trial (personnel effort, billable procedures, investigational drug services, etc.)
  - How to determine if a proposed budget is feasible
- Budget Negotiation Strategies
  - What is negotiable vs. not
  - Common pitfalls
- Activity: Budget Review

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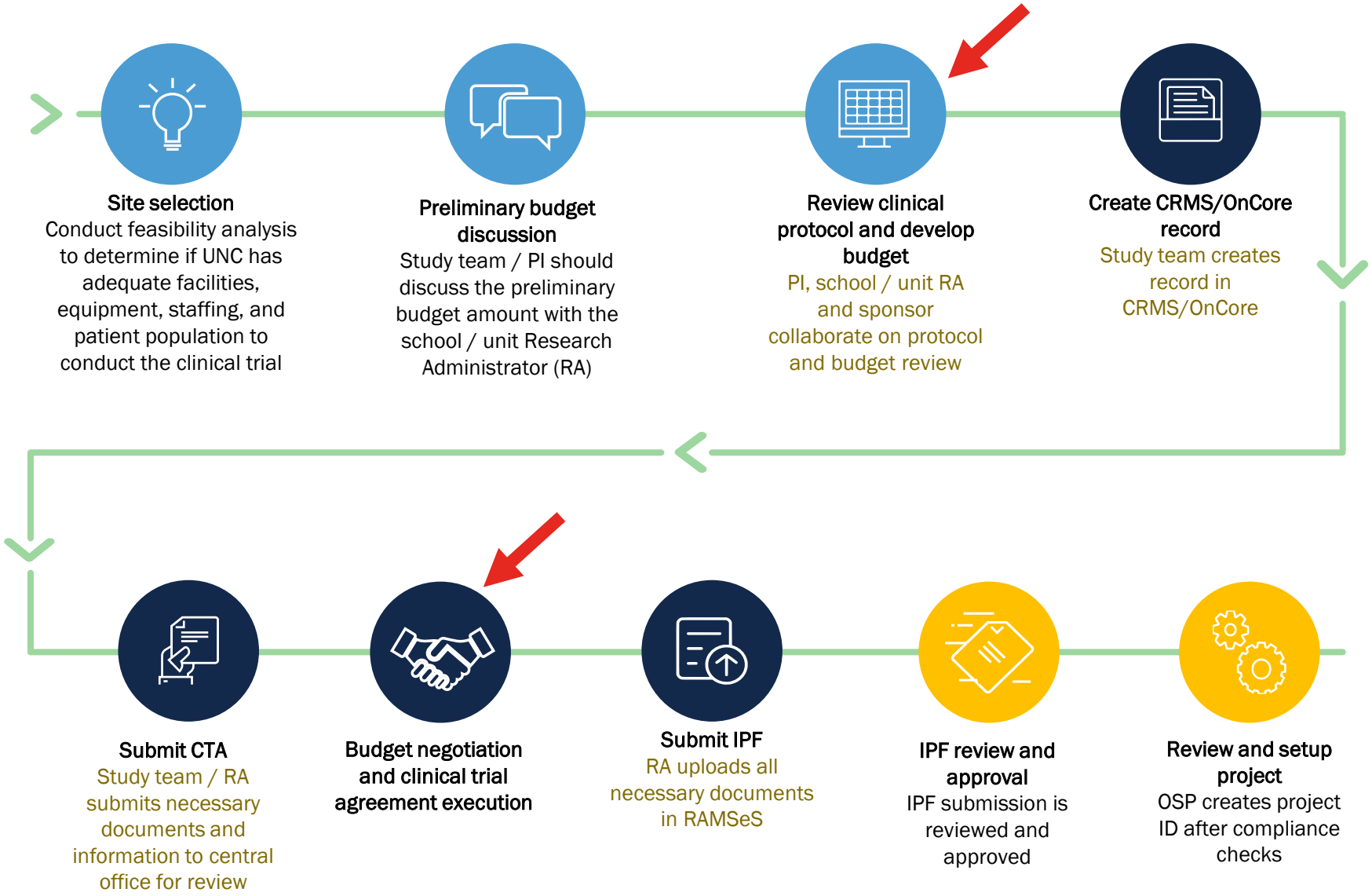
# Industry Clinical Trial Agreement (CTA) Process

# An overview of the submission and study setup journey for industry sponsored clinical trial agreements

STANDARD PROCESS FOR INDUSTRY SPONSORED CLINICAL TRIAL AGREEMENTS FROM SITE SELECTION TO PROJECT ID CREATION

**START COMPLIANCE SUBMISSIONS WHEN THE INTENT TO FUND IS CLEAR OR WHEN COMPLICATING FACTORS OCCUR**



# Roles and responsibilities in the agreement negotiation and setup process

### PRINCIPAL INVESTIGATOR (PI)

- Review sponsor agreement and provide input where necessary
- Provide approved compliance acknowledgement waiver to OSR, if applicable

### CAMPUS UNIT RESEARCH ADMINISTRATION (RA)

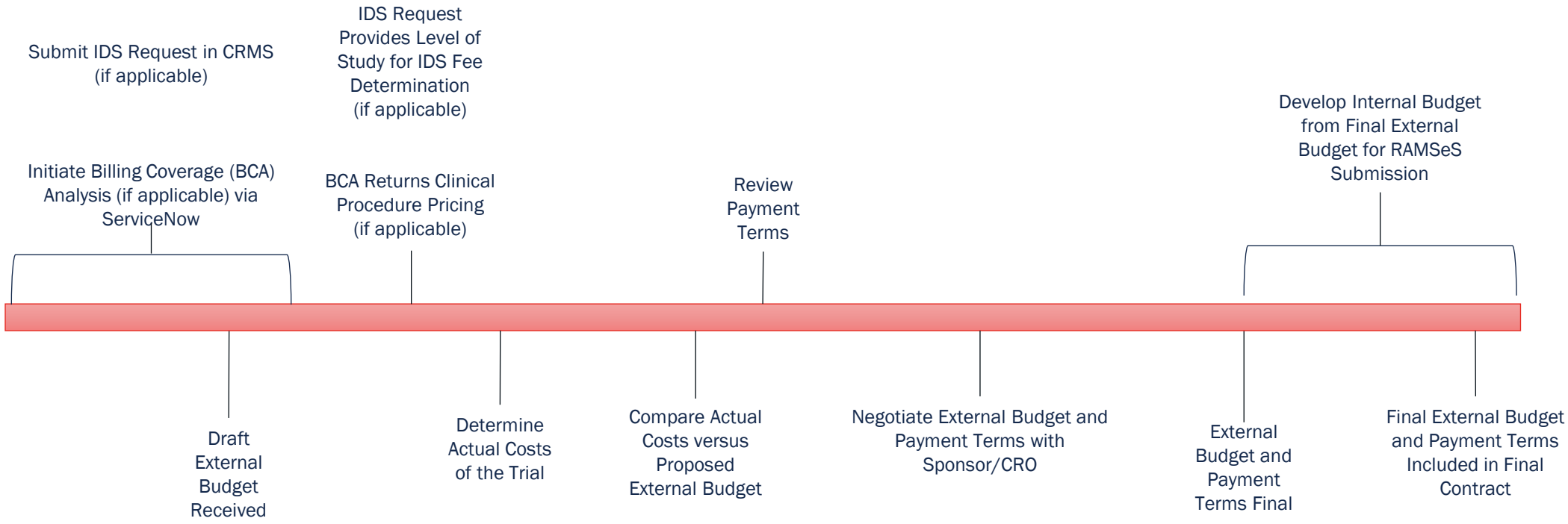
- Review sponsor agreement and provide input where necessary
- Negotiate budget and payment terms with industry sponsor
- Provide final and internal budget to OSR for inclusion in the CTA

*Note: If your department does not have a research administrator, the above responsibilities would become those of the PI / study team*

### OSP

- Industry Contracting team reviews and negotiates contract terms, confidentiality agreements, and data use agreements with the sponsor
- Complete project, budgets, and contract setup in ConnectCarolina
- Notify PI and department RA of award setup via RAMSeS email; provide chartfield and Project ID(s)
- Activate the ConnectCarolina contract

# Budget Process



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# Industry Funding Overview

# Review of Key Terms

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- Clinical Trial Agreement (CTA)
- External Budget
- Internal Budget
- Sponsor
- Contract Research Organization (CRO)
- Office of Industry Contracting (OIC)
- Billing Coverage Analysis (BCA)

# How are Industry Trials Paid?

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- Majority:
  - Automatic payments for subject visits based on data entry into electronic data capture system (EDC) (No invoice required) AND
  - Payments based on invoices generated by the research team and sent to the sponsor (referred to as "invoiceables" in the external budget and require an invoice to be paid)
- Other:
  - Milestone payments (invoice required to be paid) – ex. lump sum payments due on a certain date or when a certain number of subjects are enrolled.
  - Manual invoicing or subject visit payments (i.e. when sponsor is not automatically paying based on EDC – invoice required to be paid for all activities)

# What's an Invoiceable?

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- Something that is only paid if/when it occurs
- Payment contingent upon the sponsor/funder receiving an invoice from the site (you) - i.e. not paid automatically

# Industry Trial Payments

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- Most Industry Trials are NOT cost-reimbursement
  - Cost-reimbursement = invoicing Sponsor as charges hit the account
- Industry trials pay per the negotiated budget as study activities and milestones are completed.
- When funds are received, they are deposited into a study-specific account.  The PI (or designee) works with their finance contact to determine how the funds are spent (internal budget).

# Where do Payments Go?

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- Decided during the contract negotiation process
- Most are a physical check mailed to an address provided by the study team
- Some are paid via direct deposit

# Invoice Examples

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**INVOICE**

**PRINCIPAL INVESTIGATOR: <NAME>**
<<PI ADDRESS>>

**INVOICE # <INSERT>**
**DATE: <INSERT>**

**BILL TO:**
<ADDRESS>

**FOR:**
<PROJECT TITLE

UNC Project ID: <INSERT>

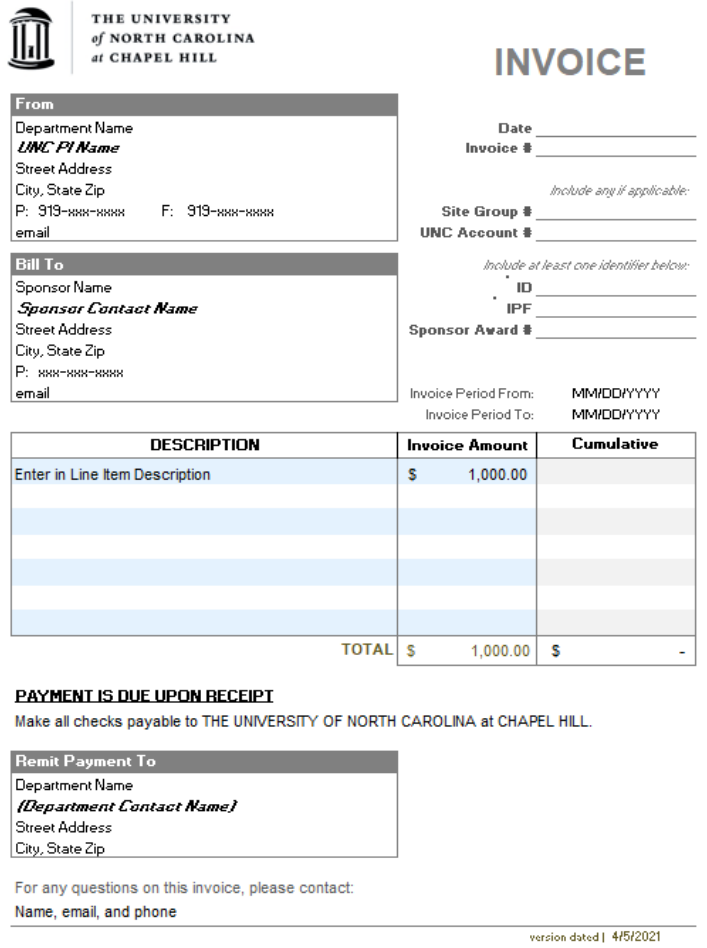
| DESCRIPTION | AMOUNT |
|---|---|
| <INSERT> | <INSERT> |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| Total Direct Costs | |
| Overhead | |
| TOTAL | |

**PAYMENT IS DUE UPON RECEIPT**

Make all checks payable to **THE UNIVERSITY OF NORTH CAROLINA at CHAPEL HILL**
If you have any questions concerning this invoice, contact <NAME> at <PHONE>, email <INSERT>

**REMIT PAYMENT TO:**
<ADDRESS>

UNC Federal Tax ID: 56-6001393



THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL

**INVOICE**

**From**
Department Name
*UNC PI Name*
Street Address
City, State Zip
P: 919-xxx-xxxx F: 919-xxx-xxxx
email

**Bill To**
Sponsor Name
*Sponsor Contact Name*
Street Address
City, State Zip
P: xxx-xxx-xxxx
email

Date
Invoice #

*Include any if applicable:*
Site Group #
UNC Account #

*Include at least one identifier below:*
• ID
• IPF
Sponsor Award #

Invoice Period From: MM/DD/YYYY
Invoice Period To: MM/DD/YYYY

| DESCRIPTION | Invoice Amount | Cumulative |
|---|---|---|
| Enter in Line Item Description | $ 1,000.00 | |
| | | |
| | | |
| | | |
| | | |
| | | |
| TOTAL | $ 1,000.00 | $ - |

**PAYMENT IS DUE UPON RECEIPT**
Make all checks payable to THE UNIVERSITY OF NORTH CAROLINA at CHAPEL HILL.

**Remit Payment To**
Department Name
*(Department Contact Name)*
Street Address
City, State Zip

For any questions on this invoice, please contact:
Name, email, and phone

version dated | 4/5/2021

Payment terms may specify additional information required on invoices. Study teams must ensure all required information is included on an invoice.

# External v. Internal Budget

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## External Budget

- The budget negotiated with the sponsor and included in the clinical trial agreement (CTA)
- The budget that decides what payments you'll receive
- If hourly rates are referenced, they use loaded/inflated hourly rates. Do not use ACTUAL rates.

## Internal budget

- Anticipated actual costs
- How you plan to spend/use the funds you anticipate receiving for the study based on the external budget.
- NOT included in the clinical trial agreement
- NOT shared with Sponsors

# External Budget Example

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| | Table 2: Schedule of Assessments | | Screening | Placebo Lead In | Treatment Phase | | | | Safety Follow Up Contact | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Procedures | Unit Costs | Visit -1 Week -6 | Visit 0 Week 0 | Randomization Baseline Visit 1 Week 4 (± 3 days) | Visit 2 Week 8 (± 3 days) | Visit 3 Week 12 (± 3 days) | Visit 4 or ET* Week 16 (±3 days) | Visit 5** Week 20 (±3 days) | Totals |
| | Week | | -6 | 0 | 4 | 8 | 12 | 16 | 20 | |
| | Window | | ≤ 6 weeks | -- | ± 3 days | ± 3 days | ± 3 days | ± 3 days | ± 3 days | |
| INCO | Informed Consent | $78 | $78 | | | | | | | $78 |
| INEX | Inclusion/Exclusion Criteria | $72 | $72 | $72 | $72 | | | | | $216 |
| 43239 | EGD w/ endoscopy score and biopsy (includes esophageal, gastric, and duodenal biopsies) includes shipping and handling | $2,500 | $2,500 | | | | | $2,500 | | $5,000 |
| 1999 | Anesthesia | $1,000 | $1,000 | | | | | $1,000 | | $2,000 |
| DPS | DSQ Compliance Assessment | $30 | | $30 | $30 | $30 | $30 | $30 | | $150 |
| EQ5D | EQ-5D | $20 | | | $20 | | | $20 | | $40 |
| QOLS | EoE-QoL-A (subjects ≥ 18 years of age) | $20 | | | $20 | | | $20 | | $40 |
| PGIS | Patient global impression of severity | $20 | | | $20 | $20 | $20 | $20 | | $80 |
| 99205 | Physical Examination: Initial Exam (includes medical history, vital signs, weight) | $180 | $180 | | | | | | | $180 |
| 99212 | Physical Examination follow up( includes vital signs, height, weight assessment) | $168 | | $168 | $168 | $168 | $168 | $168 | | $840 |
| 80299 / 99000 | Central Lab: Clinical laboratory tests (hematology, chemistry) includes shipping and handling | $80 | $80 | $80 | $80 | $80 | $80 | $80 | | $480 |
| 81000 | Urinalysis | $20 | $20 | $20 | $20 | $20 | $20 | $20 | | $120 |
| 84702 / 84703 | Pregnancy test (serum / urine) | $52 / $30 | INV | INV | INV | INV | INV | INV | | $0 |
| 82533 | Morning Cortisol | $28 | | | $28 | $28 | $28 | $28 | | $112 |
| 80400 | ACTH Stimulation testing | $185 | | | $185 | | | $185 | | $370 |
| 80299 | Pharmacokinetic sampling (3 times) | $42 | | | | INV | INV | | | $0 |
| RCM | Concomitant medications | $40 | $40 | $40 | $40 | $40 | $40 | $40 | $40 | $280 |
| ADVE | Review of adverse events (includes assessments for signs of glucocorticoid excess) | $40 | | $40 | $40 | $40 | $40 | $40 | $40 | $240 |
| | **Non-Procedures** | | | | | | | | | |
| STCO | Study Coordinator Fee (includes DSQ Training and Issue of Headset, study medication supplied and compliance) | $234 | $234 | $234 | $234 | $234 | $234 | $234 | $41 | $1,445 |
| V1110 | Investigator Fee | $180 | $180 | $180 | $180 | $180 | $180 | $180 | | $1,080 |
| VREIM | Patient Travel / Meal | $50 | $50 | $50 | $50 | $50 | $50 | $50 | | $300 |
| | **Total per Visit (without overhead)** | | $4,434 | $314 | $1,187 | $830 | $830 | $4,615 | $121 | $13,051 |
| | **Overhead** | 28% | $1,242 | $256 | $332 | $249 | $249 | $1,292 | $34 | $3,654 |
| | **Total per Visit (with overhead)** | | **$5,676** | **$1,170** | **$1,519** | **$1,139** | **$1,139** | **$5,907** | **$155** | **$16,705** |
| | **Cost per Completed Subject** | **$16,705** | | | | | | | | |

| | Site Costs | | | Total |
|---|---|---|---|---|
| 1124 | Administrative Start-Up Fee | $6,500 | $1,820 | $8,320 |
| AR01 | Document Archiving | $500 | $140 | $640 |
| | **Invoiced Procedures** | | | |
| 84702 | Serum Pregnancy Test | $52 | $15 | $67 |
| 84703 | Urine Pregnancy Test | $30 | $8 | $38 |
| 80299 | Pharmacokinetic sampling (if not collected on wk. 8) up to max. cost of | $315 | $88 | $403 |
| | Billing Coverage Analysis (required by UNC) | $2,000 | n/a | $2,000 |
| | Screen Failures (not for all) subjects who are (SF) will be paid at a rate of 2:1 based on number of subjects treated (up to 2 for every treated subject) | | | |
| | Annual IRB Review Fee (per year) | $750 | $210 | $960 |
| | IRB Amendments (per amendment) | $1,500 | $420 | $1,920 |
| | Pharmacy Setup Fee | $1,500 | $420 | $1,920 |
| | Pharmacy Fees (Monthly) | $292 | $82 | $374 |
| | Monitor Training Fee (invoiced $500/monitor) | $500 | $140 | $640 |
| | Monitoring Visits | $150 | $42 | $192 |
| | Initial IRB Fee (Central IRB) | $2,000 | n/a | $2,000 |
| V1132 | Study Coordinator / Hourly (4 hours) for PK sampling | $160 | $45 | $205 |
| | **Invoiced Total** | $16,243 | $3,430 | **$19,679** |

Automatic Payments based on EDC (typically)

Invoiceables

# Internal Budget Example

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| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| IPF: | | | | PI: | | Project Title: | | | | | | |
| Project ID: | | | Salary Cap | Due: | | PA/RFA: | | | | | | |
| | | Calendar | $ 1,000,000 | RAMSeS: | #NUM! | | | Animal Subj: | | | | |
| | | Academic | $ 1,000,000 | Project Start: | 9/1/2020 | | | Human Subj: | | | Exempt: | |
| | | Summer | $ 1,000,000 | Project End: | 8/31/2025 | | | Clinical Trial: | | | Phase III: | |
| PERSONNEL | | | | | | Year 1 | 9/1/2020 | --- | 8/31/2021 | | 364 | |
| Fringe Type | Appt | FTE | Base Salary | Personnel | Role | Salary | % Effort | PM | Salary | | Fringe | Total |
| 1 | 12 | 1 | 150,000 | NAME | PD/PI | 154,500 | 5.0% | 0.60 | 7,725 | | 2,722 | 10,447 |
| 2 | 12 | 1 | 150,000 | NAME | Co-Investigator | 154,500 | 2.5% | 0.30 | 3,863 | | 1,118 | 4,981 |
| 2 | 12 | 1 | 55,000 | NAME | Research Coordinator | 56,650 | 25.0% | 3.00 | 14,163 | | 5,098 | 19,261 |
| 2 | 12 | 1 | 45,000 | NAME | Research Assistant | 46,350 | 15.0% | 1.80 | 6,953 | | 2,675 | 9,628 |
| - | 12 | 1 | 45,000 | NAME | Research Assistant | 46,350 | 15.0% | 1.80 | 6,953 | | FALSE | 6,953 |
| - | 12 | 1 | - | | | - | 0.0% | - | 0 | | FALSE | 0 |
| | | | | Total | | | | | 39,657 | | 11,613 | 51,270 |
| | | | | Materials & Supplies | | | | | # of Units | | Price/Unit | |
| | | | | Supplies and Shipping | | | | | | | | 1,500 |
| | | | | Total | | | | | | | | $1,500 |
| | | | | Travel | | | | | #Trips | | Cost/Trip | |
| | | | | Domestic | | | | | | | | - |
| | | | | Foreign | | | | | | | | |
| | | | | Total Travel | | | | | | | | $0 |
| | | | | Other Direct Costs | | | | | # of Units | | Price/Unit | |
| | | | | IDS Fees | | | | | | | | 8,000 |
| | | | | CTRC Fees | | | | | | | | 2,000 |
| | | | | OCT Admin Fees | | | | | | | | 3,500 |
| | | | | OCT Fee Per Subject | | | | | | | | 500 |
| | | | | Patient Payments | | | | | | | | 2,500 |
| | | | | Translational Pathology | | | | | | | | 1,200 |
| | | | | Outpatient Pare Costs | | | | | | | | 8,000 |
| | | | | Total Other | | | | | | | | $25,700 |
| | | | | Total UNC Direct | | | | | | | | $78,470 |
| | | | | UNC Directs plus Subcontract Directs | | | | MAX | 499,999 | | | $78,470 |
| | | | | Indirect Cost Calcuation | | | | | | | | |
| | | | | UNC Direct | | | | | | | | $78,470 |
| | | | | Base (Excludes items not subject to OH) | | | | | | | | $74,470 |
| | | | | Indirect Total | Clinical Trials (Non-Federa | 28.00% | | | | | | $20,852 |
| | | | | Total | | | | | | | | $99,322 |

Personnel with actual salaries

Materials/ Supplies/Shipping

IDS fees, CTRC fees, OCT fees, subject payments, core charges, Hospital/Physician Charges

Overhead (F&A) Calculations

Total

# Simplified Example of External v. Internal Budget

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- External Budget

- Per patient payments:
  - Informed Consent: $100
  - Blood draw: $50
  - Physical Exam: $150
- Invoiceables:
  - Startup: $4,000
  - OCT Administrative Fees One-Time: $3,500
  - OCT Administrative Fee Per Subject: $100

Total Direct: $7,900

Total Indirect (28% F&A – excludes OCT fees):$1,204

**TOTAL: $9,104**

- Internal Budget

- Personnel
  - PI Effort: $448.75
  - CRC Effort: $3,750.00
- CTRC Level 1 Room use
  - $101.25
- OCT Administrative Fees
  - $3,500 one-time
  - $100 per enrolled subject

Total Direct: $7,900

Indirects (28% F&A – excludes OCT fees): $1,204

**TOTAL: $9,104**

*These are fictitious rates and should not be used for actual budget development with industry partners.*

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# Reviewing and Negotiating an External Budget

# Steps in External Budget Review and Negotiation

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1) Read the entire protocol and determine anticipated actual costs to run the trial
2) Determine how much funding is proposed by the sponsor (external budget) based on conservative enrollment assumptions
3) Decide if you are comfortable with what has been proposed by the sponsor, or if you need to negotiate.
4) Negotiate
5) Finalize

# Wait... How do you figure out how much it will cost?

# Step 1: Determining Actual Costs

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**Study Visit Activity Costs**

- Review the protocol, time and events table/schedule of assessments and visit descriptions
- Costs for clinical procedures determined using university's research fee schedule including both hospital and professional fees (Returned via the completed BCA)
- Determine SOC vs. research costs (Completed as part of the BCA process)
- Patient stipends/payments

**Effort Determination**

- Startup activities
- Protocol items requiring staff effort (informed consent, questionnaire completion, etc.)
- Inclusion/exclusion criteria complexity
- Data to be collected/entered (CRFs)
- Sample collection/processing
- Other administrative tasks

**Cores and Central Offices**

- Office of Clinical Trials (OCT)
- Investigational Drug Services (IDS)
- Clinical and Translational Research Center (CTRC)
- Carolina Data Warehouse (CDW)
- Core Use (Radiology, Metabolic, etc.)
- Pathology Services Core (PSC)
- Tissue Procurement Facility (TPF)
- Other costs as applicable (Advertising, etc.)

# BCA – What is It?

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- A billing coverage analysis (BCA) outlines how study activities listed in the schedule of assessments/time and events table will be billed
  - Routine* – study procedures billed to the patient as part of their routine clinical care
  - Study – study procedures billed to the study.
  - Effort – study procedures that do not incur a charge/bill and are covered by salary support/staff effort (ex. questionnaire completion, informed consent, etc.)

- If a study intends to bill study procedures to patients as routine clinical care, then the study must meet certain requirements (be considered "deemed and qualifying") to do so.

# BCA Example

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| | Screening (Visit 1) | Baseline (Visit 2; +3 days) | 12 Weeks Post Baseline (Visit 3; +/- 7 days) | 36 Weeks Post Baseline (Visit 4; +/- 7 days) | 52 Weeks Post Baseline (Visit 5; +/- 7 days) |
|---|---|---|---|---|---|
| Informed Consent | Effort | | | | |
| Eligibility Criteria Review | Effort | Effort | | | |
| Urine pregnancy testing [a] | Study | Study | Study | Study | Study |
| Headache Survey [b] | Effort | Effort | Effort | Effort | Effort |
| Medical History | Effort | | | | |
| Concomitant Medications | Effort | Effort | Effort | Effort | Effort |
| Tablet Distribution/Orientation | Effort | | | | |
| Adverse Events | Effort | Effort | Effort | Effort | Effort |
| Review Diary Compliance | | Effort | Effort | Effort | Effort |
| Weight Measurement [b] | | Effort | Effort | Effort | Effort |
| Height Measurement | | Effort | | | |
| Blood Pressure | | Effort | Effort | Effort | Effort |
| Blood Draw [c] | | Study | Study | Study | Study |
| Randomization | | Effort | | | |
| Dispense Investigational Product | | Effort | Effort | Effort | |
| Return Investigational Product | | | Effort | Effort | Effort |
| Return Tablet | | | | | Effort |

# BCA – What is it?

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- The BCA also provides hospital and professional charges of clinical study procedures for use in building your study budget and negotiating the budget with the sponsor.

# BCA

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- The BCA process is centralized and is completed by a BCA team. Requests for BCAs are submitted via ServiceNow
- **All clinical research studies MUST** submit a BCA request via **ServiceNow** as soon as the decision has been made to move forward with the study.
  - Link: https://sso.unc.edu/idp/profile/SAML2/Unsolicited/SSO?providerId=https://uncch.service-now.com&target=%2Fsp%3Fid%3Dsc_cat_item%26sys_id%3D9365df9c1bfb0190706afeee034bcb66
- Once drafted, the BCA team will contact the study PI to discuss the BCA and provide pricing (if applicable), or they will let the PI know a BCA is not required for the study.
- The BCA and research billing review process differs for the UNC Health entities. For questions and guidance regarding processes within the UNC Health network entities please email ORSC@unchealth.unc.edu
- More information about the BCA process: https://research.unc.edu/clinical-trials/bca/

# Required UNC Fees

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- Office of Clinical Trials Administrative Fees ($3500 + $100 per subject enrolled)
  - https://research.unc.edu/clinical-trials/budgets/required-costs/
- Overhead/F&A
  - https://research.unc.edu/clinical-trials/budgets/required-costs/
- IDS fees (if applicable)
  - Based on calculated level and activities performed by IDS – see website for current pricing https://uncids.web.unc.edu/

# Resources

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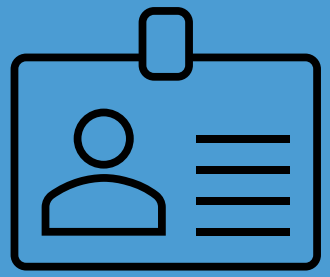
Need a budget template or tools to help estimate personnel and administrative costs? Try this!
https://research.unc.edu/clinical-trials/budgets/tools/

Refer to CTRC, IDS, Core, etc. website for current fees.



For help with obtaining research rates, contact the Office of Clinical Trials resbilling@unc.edu

# Step 2: Compare Actual Costs to Proposed Budget

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- Review the proposed external budget provided by the Sponsor/CRO against the actual costs you anticipate incurring.
- Is it more, less, equal to?

# Step 3: Decide if You Want to Negotiate

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- Always negotiate!
- At minimum, a budget is acceptable if it covers your anticipated costs of running the trial.
- Ideally, an industry-sponsored budget covers more than cost, and that's perfectly OK.
- Some studies may be conducted at a loss for scientific or patient-care related reasons. PIs should discuss these situations with their department to determine how the loss will be covered.
- After an industry-sponsored study is completed, excess funds may be moved to an investigator's or departmental residual account for future use.

# Step 4: Negotiate

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- In addition to negotiating the budget, keep in mind you must also review and negotiate payment terms, such as:
  - What triggers payments?
  - What items will be paid automatically versus those requiring an invoice to be sent?
  - How will you be paid (paper check or direct deposit)?
  - Restrictions on payments such as enrollment caps, screen fail limits, etc.
  - Documentation required to be paid – ex. what does "supporting documentation" mean?
  - Insert comments on the payment terms where you need clarification, and/or make changes using tracked changes to request revisions to the Sponsor.

# What Does the Negotiation Process Look Like?

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*“This costs more than every other site.”*

*“UNC is the most expensive site.”*

*"This is the maximum I'm authorized to offer“*

*“A recently negotiated budget with UNC accepted this offer”*

# Negotiation Tips

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- Everything proposed by the Sponsor/CRO in the budget is negotiable (even if they say it isn't!).
- UNC has some fees that are non-negotiable.  Even if a sponsor does not approve these fees, the study is still required to pay them.

# What can I negotiate with an Industry Sponsor?

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## Negotiable Costs

- Per-procedure payments (ex. Informed consent, blood draw, physical exam, etc.)
- Invoiceables such as:
  - Start up costs
  - Close out costs
  - Monitoring and auditing costs
  - Some department or other administrative fees

## Non-Negotiable Costs

- Overhead rates*
- Institutional administrative fee ($3,500 start and $100/patient)
- Hospital/Professional charges
- IDS fees
- CTRC fees
- Other University Core fees
- Some department fees
- *Note: this is not an inclusive list*

# Negotiation Tips

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- Add invoiceables
  - Sponsors/CROs will require justification on letterhead for most added invoiceables or requests you have that are considered "excessive" in their eyes.
  - Save time by standardizing the clinical trial invoiceables you want and create a summary packet to share with Sponsors/CROs that includes justifications for all of your asks.
- If dealing with a CRO and not directly with a sponsor, when the CRO rejects your budget requests, then request they escalate the budget to the Sponsor for approval.
- Be willing to accept counter offers on some items.

# Suggested Additional Invoiceables

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- Start-up fees
- PRN procedures
- SAEs (per occurrence)
- Screen failures
- Re-consenting fee (if applicable)
- Additional incentive programs/advertising costs
- Protocol amendment administrative fee (paid per protocol amendment)
- IRB administrative fee (paid per IRB submission initiated by site)
- Annual regulatory maintenance fee
- Monitoring visit fees (paid per visit, per day, or per hour)
- Monitor training or change fees
- Site audit fee (paid per audit, per day, or per hour)
- Document storage and archiving
- Study closeout

# Step 5: Finalize

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- Notify OSP contract manager of final negotiated budget and payment terms
- Develop internal budget from final external budget for RAMSeS record

# Common Pitfalls

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- Lack of clarity in payment terms leading to confusion about how payments will be received
  - What requires an invoice, what will be paid automatically? How often are you required to invoice?
  - Are they sending a check, and if so, what mailing address are they using?
  - Or are they issuing payment via direct deposit, and if so, do they have the correct banking information?
- Payment triggers referenced in the payment terms (monitored data, etc.) do not ensure timely payment/result in delayed payment
- Lack of understanding of protocol requirements/underestimating personnel effort required to execute the study
- Not taking the time to calculate true costs of the study and effort involved
- Accepting a budget without negotiating
- Relying solely on the schedule of assessments in the protocol and not reviewing the protocol in its entirety to determine costs
  - Sometimes hidden costs of the study are buried in the protocol and not referenced in the schedule of assessments.
- Unanticipated cost/effort and potential costs/drug not budgeted
- Disconnect between study team and invoicing team (if they are separate groups)


# Quick Practice!

| | Screening (Visit 1) | Baseline (Visit 2; +3 days) | 12 Weeks Post Baseline (Visit 3; +/- 7 days) | 36 Weeks Post Baseline (Visit 4; +/- 7 days) | 52 Weeks Post Baseline (Visit 5; +/- 7 days) |
|---|---|---|---|---|---|
| Informed Consent | X | | | | |
| Eligibility Criteria Review | X | X | | | |
| Urine pregnancy testing [a] | X | X | X | X | X |
| Headache Survey [b] | X | X | X | X | X |
| Medical History | X | | | | |
| Concomitant Medications | X | X | X | X | X |
| Tablet Distribution/Orientation | X | | | | |
| Adverse Events | X | X | X | X | X |
| Review Diary Compliance | | X | X | X | X |
| Weight Measurement [b] | | X | X | X | X |
| Height Measurement | | X | | | |
| Blood Pressure | | X | X | X | X |
| Blood Draw [c] | | X | X | X | X |
| Randomization | | X | | | |
| Dispense Investigational Product | | X | X | X | |
| Return Investigational Product | | | X | X | X |
| Return Tablet | | | | | X |

a. Urine pregnancy testing to only be performed for women of childbearing potential. A woman of childbearing potential is defined as any woman who has begun menstruating. Women who are post-menopausal (over the age of 40 and has not had a period in 12 months) or surgically menopausal (e.g. total abdominal hysterectomy) are not considered of childbearing potential and do not have to have urine pregnancy testing completed.
b. Headache survey should be completed prior to any study procedures, but after any informed consent processes.
c. Weight measurements should be taken on a scale that is calibrated the day of the measurement.
d. Blood pressure should be taken after the participant is seated for five minutes, and prior to the blood draw. The same arm must be used for the measurement throughout the study.

# Screening Visit Only – Estimated Actual Costs

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| | Screening (Visit 1) | Description | Amount |
|---|---|---|---|
| Informed Consent | X | PI Effort and CRC Effort in identifying, pre-screening, contacting subject, scheduling a visit, reviewing/completing/and docmenting the consent | 0.5hr PI<br>1hr CRC |
| Eligibility Criteria Review | X | PI and CRC Effort | 0.5hr PI<br>0.5hr CRC |
| Urine pregnancy testing | X | CTRC Room Use – Level 1 Care OR Performed by hospital | $101.25 or $30 |
| Headache Survey | X | CRC Effort | 0.25hr CRC |
| Medical History | X | PI Effort | 0.5hr PI |
| Concomitant Medications | X | CRC Effort | 0.25hr CRC |
| Tablet Distribution/Orientation | X | CRC Effort | 0.25hr CRC |
| Adverse Events | X | PI and CRC Effort | 0.25hr PI<br>0.25hr CRC |
| | | CRC Effort in preparing for visit - reserving room, printing materials, etc. | 0.5hr CRC |
| | | CRC Effort for data entry after the visit | 0.5hr CRC |
| | | CRC administrative effort such as post-visit follow-up with patient to schedule next visit | 0.5hr CRC |

*Don't forget there are tools available to help you create these estimates*
*https://research.unc.edu/clinical-trials/budgets/tools/*

Total PI Effort: 1.75 hours
Total CRC Effort: 4 hours
Total Billed Costs: $101.25 (if using CTRC)

# Actual Screening Visit Cost (Estimate)

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| | |
|---|---|
| PI Effort: 1.75 hours + fringe and benefits @ $100/hr | $175.00 |
| CRC Effort: 4 hours + fringe and benefits @ $50/hr | $200.00 |
| CTRC Room Use Fees | $101.25 |
| Total Direct | **$476.25** |
| Indirects (28%) | $133.35 |
| **Total** | **$609.60** |

*Assumptions:*

- *Actual PI salary + fringe and benefits: $100/hour*
- *Actual CRC salary + fringe and benefits: $50/hour*

# Proposed External Budget and Suggested Counter - Screening Visit

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| Paid per EDC | Proposed by External Budget (Direct Cost) | Suggested Counter (Direct Cost) |
|---|---|---|
| Informed Consent | $80 | $150 |
| Eligibility Criteria Review | $40 | $75 |
| Headache Survey [b] | $20 | $30 |
| Medical History | $40 | $100 |
| Concomitant Medications | $20 | $50 |
| Tablet Distribution/Orientation | $30 | $50 |
| Adverse Events | $50 | $75 |
| **Invoiceables** | | |
| Urine pregnancy testing | $20 | $30 |
| **Total Direct** | **$300** | $560 |

Goal: To exceed your estimated actual cost (direct) of the screening visit ($476.25)

# Goal of Negotiations

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- The main goal of negotiations is to ensure proposed payments meet or exceed your actual cost estimate
- It's important to look at the budget as a whole
  - Ex. a low payment for a screening visit may be off-set via "excess" payment for other visits or approval of additional invoiceables

# Resources Reminder

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- Tools for estimating cost of study:
  - https://research.unc.edu/clinical-trials/budgets/tools/
- UNC Required Fees for Industry:
  - https://research.unc.edu/clinical-trials/budgets/required-costs/
- IDS Fees:
  - https://uncids.web.unc.edu/
- CTRC Fees:
  - https://tracs.unc.edu/index.php/services/ctrc/ctrc-operations/fees


# Additional Questions/Discussion?