Industry-Sponsored Clinical Trial Budgeting

Building Clinical Trial Budgets for Full Recovery of Costs

Presented by:
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Clinical Agreements Team Contact Information
Welcome

- Why are you here today?
- To better understand the budget development process for clinical trials
- To learn what can and cannot be included in a clinical trial budget while ensuring expenditure recovery for industry (non-federal) sponsors
- To ensure clinical trial budgets and subsequent billing are in accordance with regulatory and sponsor requirements
Topics Covered

- Roles and Responsibilities
- Budget Development
- Negotiation
- Consistency Review
- Budget Monitoring
- Case Studies
- Test Your Knowledge
- Key Points to Remember

Last slides include: Glossary, Resources, a list of websites referenced in class
Roles & Responsibilities

Budget Development
Negotiation
Consistency Review
Budget Monitoring
Case Studies & Questions
Roles and Responsibilities

**PI**
- Develops protocol for investigator-initiated trials (IITs)
- Budget approval

**YNHH & Yale ISPs**
- Set rates for certain procedures

**YCCI**
- May prepare, develop & negotiate budget with sponsor

**DBO**
- Budget development and negotiation (may include study coordinator)
- Confirms budget is consistent with informed consent documents (ICF)

**OSP**
- Contract negotiation
- Reviews & confirms consistency between contract, budget & ICF
- Ensures final contract includes final negotiated budget

**Sponsor**
- Develops protocol
- Negotiates budget
- Reviews and approves ICF
Roles and Responsibilities: Who funds clinical trials?

- **Funding Sources**
  - **Industry (pharmaceutical and device companies)**
  - **National Institutes of Health (NIH)**
    - Other U.S. Federal agencies (e.g., Centers for Disease Control and Prevention (CDC), Cancer Oncology Groups (COG)).
  - **Other sources such as collaborative agreements with foundations, universities via subawards, and community-based organizations or internal (Yale) department support.**
When there is PI interest in the trial and a study protocol:

- The Principal Investigator (PI) and/or Study Coordinator meet with the Department Business Office (DBO) to begin the process of creating the trial budget
  - The earlier this occurs, the better.
- Is there a sufficient pool of potential subjects and resources to run the type of study?
  - The number of subjects to be enrolled and duration of the trial are key to creating an accurate budget.
- Is the sponsor proposed budget adequate to support the work/tests/procedures described in the protocol?
Roles & Responsibilities – Preparation & Feasibility Phase

- Department Business Office (DBO) or YCCI will assist with budget development by contacting YNHH to gauge current rates for ancillary or outpatient services.
  - May require contact with the hospital billing section for determination of specialty procedure costs (outside of the Charge Master) performed by YNHH personnel
  - May require contacting internal service providers (ISPs) or departments, such as the YNHH pharmacy or the Yale PET Center to correctly budget for all appropriate costs
  - May require Medicare Coverage Analysis (MCA)
Roles & Responsibilities – Preparation & Feasibility Phase

- Requirements of Yale Policy 1316 on Effort Commitment: Managing Effort Associated with Sponsored Projects
- Clinical trials require some commitment of effort on the part of the Principal Investigator (PI) and any Sub-Investigators (Sub-Is) paid by the clinical trial award
- Review Policy 1315.03: Establishment of Salaries on Sponsored Project Accounts
Roles & Responsibilities

Budget Development

Negotiation

Consistency Review

Budget Monitoring

Case Studies & Questions
Phases of clinical trials can impact budget development

- Phase I
  - Usually a shorter study length
  - Less is known about potential Adverse Events (AEs)
  - Include per incident reporting fee for each AE & SAE that occurs to help recover the PI time needed (AE & SAE fees are appropriate for other phases as well).

- Phase II & III
  - Can lead into extended study phases or excessive patient monitoring past the study end date.

- Phase IV (post marketing)
  - Sponsors may try to not pay for the study drug or device because of its approved marketed status.
Device trials

- For device trials, consideration must be given to the following:
  - Is the sponsor providing the device for free?
    - If not, is YNHH going to purchase the device and submit to subjects’ insurance for reimbursement/coverage?
  - Coordination with YNHH will be necessary to ensure that any purchase agreement between YNHH and the sponsor (if sponsor is not providing the device for free) is consistent with the clinical trial agreement and budget.
Three areas of a Clinical Trial Budget

Subject Costs
- The direct costs of:
  - A single individual subject completing the clinical trial (multiplied by)
  - The anticipated number of subjects to be enrolled

Other Direct Costs
- Non-subject charges for the study
- Known and predictable costs (e.g., pharmacy fee, adverse event (AE) reporting, archiving/record retention fee, etc.)

Invoiceable Costs
- Events that may or may not occur during the course of the trial that are billed to sponsor ONLY if activity occurs (e.g., screen failures)
- Subject stipend, if any
**Budget Development**

- **Create a study calendar using the study protocol**
  - Plot out the total number of visits and procedures needed at each (be certain that a Yale procedure accurately matches the protocol description of that procedure).
  - Via OnCore, look up any YNHH procedural costs (research rates) from the YNHH ChargeMaster. Keep in mind that procedural costs may not include/cover the professional fee.
  - Identify Standard of Care (SOC) costs that are not normally included in the research costs (double billing concern).
  - The protocol’s procedure calendar will most likely NOT include all of the time needed by study personnel (e.g., technical fee for procedures does not include or cover the professional fees needed). Therefore, any professional time should be calculated (per hour, per visit, or per subject, etc.) and applied to the budgeted study costs.
  - Subject stipend, if any.
Budget Development

- **Consider the overall study design and duration**
  - Determine study duration (months, years) and whether yearly inflation increases are appropriate to include
  - Accrual goals (enrollment) over the course of the study
  - Is there a post-study follow up period? How long might any study extensions last? What are the associated costs?

- **Identify any reasonable study costs that may not be included in the sponsor’s budget**
  - e.g., pharmacy and laboratory services, adverse/serious adverse event (AE/SAE) reporting, re-consenting, audits, archiving records, etc.
Budget Development

- Identify potential invoiceable costs related to an industry funded (non-Federal) clinical trial
  - Advertisements in line with IRB Policy 410 Recruitment of Research Participants
  - Re-consenting
  - Audits
  - Excessive monitoring visits (e.g., more often than every 6 – 8 weeks)
  - Charges for Minor/Major Protocol amendments during the study
  - Subject reimbursement for long distance travel to clinics or offsite locations
    - Hotel, Mileage/Tolls, Meals
  - Certain closeout costs (Queries, sponsor closeout)
Cost of Institutional Review Board (IRB) Reviews

- Invoiceable costs
- The budget must clearly indicate that IRB fees:
  - Are billed directly by the IRB separate from any other fees,
  - Are not part of any start-up costs invoiced by the Department, and
  - Are not limited in term or number.
- IRB fees are charged to industry (for profit) and non-profit sponsors (unless the non-profit sponsor has a written policy against paying IRB fees), on both sponsored and investigator-initiated studies.
  - F&A rate is not applied to IRB fees.
Budget Development – IRB Fees

- **Current IRB Fee Structure:**
  - Initial review of protocol and associated material $3,000.00
  - Continuing review (required annually or less than) $1,500.00
  - Major amendment (requiring review by full committee) $700.00
  - Minor (Expedited) amendment $500.00
  - Closure $250.00

Yale HRPP charges an IRB administrative review fee for protocols reviewed by an external IRB

- Initial review of protocols submitted to an external IRB $2,000.00
- Continuing review $750.00
- Amendment $600.00
- Closure $100.00
Budget Development

Non-Federal vs. Federal Clinical Trials

- **Non-Federal Clinical Trial**
  - Most industry sponsors will provide a proposed budget at the very start of the negotiations.
  - Yale’s F&A rate is 30%

- **Federal Clinical Trial**
  - Develop a proposed study budget in order to respond to the Federal request for proposal (RFP). Awards may fall short of requested amounts.
  - Salary cap may apply based on sponsor.
  - Yale’s negotiated Federal F&A rate is higher than non-Federal (industry).

  **Note:** Study development, reporting, and record retention costs are covered by the federal F&A.

*Federal clinical trials are not handled by OSP Clinical Trials Team*
How to build a protocol calendar of costs for procedures
### Review protocol calendar for procedures and timing

**Sponsor Study Protocol: Calendar of Events**

A Multicenter Double-Blind Trial Evaluating [Study Drug] Efficacy in Patients with [Diagnosis]

<table>
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<th>Week</th>
<th>Phase 1</th>
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<td>8</td>
<td>Biomarker samples(^a)</td>
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\(^a\) Biomarker samples will be collected, aliquoted, labelled, stored at -80°C until the end of the month, and then shipped on dry ice to the central lab.
Assign each procedure cost to Yale or DBO spreadsheet.
Budget Development

- Look up costs on YNHH ChargeMaster via OnCore
- Must calculate costs of procedures NOT listed in OnCore
- Add the YMG professional fee and YNHH technical fee (where appropriate) to determine the total research rate
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**Subtotal of Direct Costs:**
- Medical Hx and TS assessment: $116.00
- Physical Exam: $175.00
- Demographics/Risk factors: $0.00
- Completion of eCRFs: $278.00
- Vital Signs (weight, HR, BP): $294.00
- Concomitant medications: $160.00
- Creatinine: $214.00
- 12 Lead ECG: $1,420.00
- 6-MWT: $455.00
- Biomarker samples: $2,250.00
- Data Entry: $310.00
- Study Coordinator fee: $372.00
- 3-MNT: $576.00
- Study Subject Stipend: $250.00
- Other invoiceable costs: $3,200.00
- Other procedures: $1,420.00

**Subtotal of Direct Costs:**
- Administrative Startup: $3,380.00
- Administrative Close-Out: $3,900.00
- Archiving Fees: $3,250.00
- Pharmacy Start-Up / Close-Out Costs: $3,900.00
- Pharmacy Quarterly Management Fees: $4,420.00
- Prep Fee for IRB Protocol Amendment: $225.00
- Prep Fee for IRB Annual Reapproval: $225.00

**Total Other Direct Costs:**
- Administrative Startup: $3,380.00
- Administrative Close-Out: $3,900.00
- Archiving Fees: $3,250.00
- Pharmacy Start-Up / Close-Out Costs: $3,900.00
- Pharmacy Quarterly Management Fees: $4,420.00
- Prep Fee for IRB Protocol Amendment: $225.00
- Prep Fee for IRB Annual Reapproval: $225.00

**Total Estimated Project Costs:**
- Direct Costs: $5,669.00
- Indirect Costs: $1,700.70
- Total: $7,369.70
Subject Stipend vs. Subject Reimbursement

- **Subject stipend** = a payment that a research subject may receive as compensation for his/her participation in the clinical trial.
  - Typically, fixed amounts that are paid to a subject based on the completion of a study visit
  - Generally included as part of the per-visit cost paid for by the sponsor/funding agency
  - Differs from reimbursement for actual expenses
Subject reimbursement = when a research subject is reimbursed for actual expenses incurred during his/her participation in a clinical trial

- Reimbursable activity may include mileage, parking, lodging or meals
- Study coordinators should be collecting receipts, which are required
- Sponsor may limit such reimbursement (e.g., mileage is paid for research participants who travel more than a set number of miles to come to Yale for study visits or for hotel visits up to a specified amount per day)
Subject Stipend/Reimbursement: F&A Rate

• F&A rate of 30% applies to both subject stipends and subject reimbursement.

• For example, a $50 stipend in the budget does not equate to $50 in the ICF unless the overhead is separately added in the budget. If the $50 in the budget is inclusive of overhead, the subject will receive only $38.46 for a subject stipend.

• Similarly, if the budget provides travel reimbursement of up to $50 (inclusive of overhead), the subject can be reimbursed up to $38.46 for travel expenses.
Budget Development – OnCore

- **OnCore: Yale’s Clinical Trial Management System (CTMS) must be used for:**
  - ALL Yale clinical trials that have billable services
  - ALL Yale School of Medicine (YSM) clinical trials offering participant remuneration on or after 1/1 2018 (*Procedure 3417 Human Research Study Participant Remuneration*).

- Provides an infrastructure for managing clinical trials (clinical, regulatory, financial and administrative) including the following:
  - **Budgeting** and invoicing
  - Canned and custom reporting technology
  - Data and safety monitoring
  - Effort tracking module
  - Electronic data capture and data management
  - FDA annual reports
  - Protocol and subject life cycle management
  - Security
  - Subject visit tracking
  - Task management

*Visit the [Oncore website](http://oncore.com) for more information*
Budget Development – OnCore

- Advantages of OnCore
  - Automates portions of budget creation
  - Features ability to differentiate budget expenses:
    • Research vs. Standard of Care
Yale Center for Clinical Investigation (YCCI)

- The PI, DBO or Study Coordinator can work with the YCCI research budget development unit to create the clinical trial budget.

- YCCI builds the trial calendar and develops the budget in OnCore, and will negotiate the budget with the sponsor.

- YCCI currently prepares and negotiates budgets for clinical trials conducted by the Yale Cancer Center, Endocrinology, Surgery, Dermatology, Urology, as well as some Neurology, Neurosurgery, and Gynecology studies.

- YCCI also provides Medicare Coverage Analysis (MCA).
Roles & Responsibilities
Budget Development
Negotiation
Consistency Review
Budget Monitoring
Case Studies & Questions
Clinical Trial Budget Negotiation with Sponsor

- Expect the sponsor to have a lower cost budget in mind

- **Prepare for the budget negotiation**
  - Know the study details (e.g., use of central or local labs, any necessary equipment, or if supplies and shipping are needed)
  - Know the study costs (research-related charges, hidden items)
  - Know the budget (one offered by sponsor vs. one developed based on Yale costs)

- **Be positive**

- **Be reasonable**

- **Be prepared to make concessions or trade-offs**
  - May need to raise costs in one category in order to compensate for deficiencies in another category
Clinical Trial Budget Negotiation Tips

Common Sponsor “Lines”

“Your costs are the highest of all the trial locations.”
“Every other site has accepted this budget but you”

*Response: Costs can vary due to region or size of institution, but these are our actual costs required to conduct the study appropriately.*

“The budget is not negotiable”
“It’s your responsibility as a site doing research to pay for that... It’s just the cost of doing business.”
“We are only authorized to go up to $----”

*Response: These are our actual costs. We cannot operate at a deficit or fund your research.*
Clinical Trial Budget Negotiation with Sponsor

- Important to keep OSP “in the loop” regarding budget negotiations, in part, so that OSP can keep the contract review/negotiation and informed consent consistency review on track and running in tandem.

- Study documentation (clinical trial agreement, budget, study protocol and informed consent form(s) (ICF(s))) must be consistent with one another.
Roles & Responsibilities
Budget Development
Negotiation
Consistency Review
Budget Monitoring
Case Studies & Questions
Consistency Review

- There must be consistency across all clinical trial documents
  
  • e.g., the clinical trial agreement, budget, study protocol and informed consent form(s) (ICFs)

- OSP, with assistance and support from budget negotiators, review ICFs for consistency with the clinical trial agreement, including the budget, with a focus on the Economic Considerations and In Case of Injury (research-related subject injury) sections

  • Use HRPP Consent Glossary and template language for consents and compound (consent & RAF) authorization forms (located in the IRES IRB Library tab)
Consistency Review

- A member of the OSP Clinical Trial Agreements team will review and sign-off on every ICF associated with an industry-supported clinical trial to ensure that Economic Consideration and Subject Injury terms are consistent with the negotiated terms of the clinical trial agreement and budget.

  • OSP works directly with the HRPP to complete this review process regardless of whether the study is under the purview of the Yale IRB or an External IRB.

  • Any revisions to the ICF as the result of the review will be requested by Yale IRB (if Yale IRB is the IRB of Record) or by the HRPP via the authorization letter (if an External IRB will be the IRB of Record).
Roles & Responsibilities
Budget Development
Negotiation
Consistency Review
Budget Monitoring
Case Studies & Questions
Clinical Trial Budgeting – Monitoring

- Monitoring of trial costs
  - Throughout the trial, the following items should be reviewed and confirmed:
    - The predicted costs are still in sync with budgeted amounts
    - The enrollment numbers and time frame for completion are still realistic
  - Evaluate any protocol changes or amendment requests that arise and alert both OSP & the IRB to those changes.
  - Verify that no unanticipated costs have been discovered (e.g., more screen failures are occurring than anticipated).
Clinical Trial Budgeting – Monitoring Payments

Payment Method = Per Unit/Procedure

- Payments should be based on actual work conducted, and the specific items and/or services rendered as listed in the Clinical Trial Agreement, including the budget.

- OnCore can aid with invoicing and tracking of procedural costs.
  - View the OnCore website for more information
Roles & Responsibilities

Budget Development

Negotiation

Consistency Review

Budget Monitoring

Case Studies & Questions
Test Your Knowledge
Q1: True or False?

The F&A rate for clinical trials is 30%.

Answer: ?
Test your knowledge...

Q1: True or False?

The F&A rate for clinical trials is 30%.

Answer: It depends...

It depends on the funding source/sponsor.

- The F&A rate for non-federal clinical trials (excluding federal pass-through) is 30%.
- The F&A rate for federally funded clinical trials are budgeted at the appropriate federal negotiated F&A rate.
Q2: True or False?

The PI, DBO, and/or YCCI may negotiate industry clinical trial budgets.

Answer: ?
Q2: True or False?

The PI, DBO, and/or YCCI may negotiate industry clinical trial budgets.

Answer: True

- The PI and DBO may negotiate the industry sponsored clinical trial budget with assistance from OSP.
- YCCI’s research budget development unit provides budget development and negotiation services for those Departments or researchers who have arranged to receive such services.
Q3: ABC Pharmaceuticals, Inc. is offering a budget that covers $5,000 per subject enrolled and no other costs. The PI has reviewed and approved the budget. Should the business office send this budget on to OSP as the final budget for inclusion in the contract?

Answer: ?
Q3: ABC Pharmaceuticals, Inc. is offering a budget that covers $5,000 per subject enrolled and no other costs. The PI has reviewed and approved the budget. Should the business office send this budget on to OSP as the final budget for inclusion in the contract?

Answer: No

• A detailed Yale budget must be prepared that captures all of Yale’s study costs, including the subject costs, other direct costs (e.g., start-up costs, pharmacy, record retention, etc.), and invoiceable costs (e.g., IRB fees), plus a 30% F&A rate before the budget is finalized.

• Even if the $5,000 per subject cost is found to be adequate to cover the per subject costs, there are likely to be other costs that need to be included in the final budget.
Q4: ABC Pharmaceuticals, Inc. believes that IRB fees should be part of the startup costs and wants to roll everything into a single startup cost. Is that acceptable?

Answer: ?
Q4: ABC Pharmaceuticals, Inc. believes that IRB fees should be part of the startup costs and wants to roll everything into a single startup cost. Is that acceptable?

Answer: No

- IRB fees are separate and need to be visible to allow billing of the sponsor by the Yale HRPP.
- In addition, IRB fees are not subject to the 30% F&A rate that would be applied if combined together with the startup costs.
KEY POINTS TO REMEMBER

- A 30% F&A rate (excluding IRB fees) is applied to industry-sponsored clinical trials.
- Clinical trial budgets should cover Yale’s costs of conducting the trial. Do not simply accept the proposed budget from the sponsor without considering the cost of conducting the trial at Yale.
- Important to keep OSP “in the loop” regarding budget negotiations, in part, so that OSP can keep the contract review/negotiation and informed consent consistency review on track and running in tandem.
- OnCore, Yale’s Clinical Trials Management System (CTMS), must be used for clinical trials with billable services.
Glossary

Additional Resources

and

Websites referenced in this presentation
Clinical Trial

“A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.”
(NIH definition)

- Single-center Study
  - A clinical trial that takes place at one clinical site.
- Multi-center Study
  - A clinical trial that takes place at multiple clinical sites.

Informed Consent

A process in which researchers communicate with potential and enrolled participants about a clinical study.
Glossary

Sponsor
The person/organization responsible for overseeing the clinical investigation (clinical trial) and for reporting the study data

Sponsor Initiated Clinical Trial
Study protocol is developed by the industry sponsor

Investigator-Initiated Clinical Trial (IIT)
Study protocol is developed and proposed by the investigator

Medicare Coverage Analysis (MCA)
Determination if Medicare covers the routine costs of qualifying clinical trials, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials
Websites referenced in this presentation

Clinical Agreements Website
https://your.yale.edu/research-support/office-sponsored-projects/clinical-agreements

Clinical Agreements Team Contact Information
https://your.yale.edu/policies-procedures/other/clinical-trial-management-portfolio-matrix

Policy 1315.03: Establishment of Salaries on Sponsored Project Accounts
https://your.yale.edu/policies-procedures/policies/1315-effort-reporting-certifying-effort-sponsored-projects#1315.03

IRB Policy 410 Recruitment of Research Participants
https://your.yale.edu/policies-procedures/policies/410-irb-policy-410-recruitment-research-participants

Institutional Review Board (IRB) Review Fee Schedule
https://your.yale.edu/sites/default/files/irbfeescheduleaugust32015.pdf

OnCore and OnCore Medicare Coverage Analysis (MCA)
http://oncore.yale.edu/
https://medicine.yale.edu/ycci/oncore/availableservices/medicarecoverageanalysis/

OSP Industry-Sponsored Clinical Trial Process
https://your.yale.edu/policies-procedures/other/osp-industry-sponsored-clinical-trial-process

IRES IRB Library (you may need to log into IRES before clicking this library link)
https://ires-irb.yale.edu/IRB-PROD/Rooms/DisplayPages/LayoutInitial?Container=com.webridge.entity.Entity%5bOID%5b75456C0548ED043B88308FA6D00E090%5d%5d
Additional Resources

- **University Policy and Procedures:**
  - IRB Fee Schedule
    - [http://your.yale.edu/policies-procedures/other/irb-fees-schedule](http://your.yale.edu/policies-procedures/other/irb-fees-schedule)
  - IRB Policy 410 Recruitment of Research Participants
    - [http://your.yale.edu/policies-procedures/policies/410-irb-policy-410-recruitment-research-participants](http://your.yale.edu/policies-procedures/policies/410-irb-policy-410-recruitment-research-participants)
  - Policy 1316 Effort Commitment: Managing Effort Associated with Sponsored Projects
  - New Study setup for Oncore:
    - [http://medicine.yale.edu/ycci/oncore/availableservices/newstudysetup/index.aspx](http://medicine.yale.edu/ycci/oncore/availableservices/newstudysetup/index.aspx)
  - Procedure 3417 PR.01 Human research Study Participant Remuneration
    - [https://your.yale.edu/policies-procedures/procedures/3417-pro1-human-research-study-participant-remuneration](https://your.yale.edu/policies-procedures/procedures/3417-pro1-human-research-study-participant-remuneration)
Additional Resources

- **Federal Resources:**
  - National Coverage Determination (NCD) for Routine Costs in Clinical Trials (310.1)
  - ClinicalTrials.gov
Email questions to: osp.trainings@yale.edu
Response will be forthcoming within 2 business days.