Basics of Developing Study Budgets in Clinical Research

Office of Research Administration (ORA)

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Learning Objectives

• Recognize what your role and the institution’s role and responsibilities are when developing a research budget.
• Understand the components of building a clinical research budget.
• Know the differences between different clinical research study budgets.
• Recognize the institutional costs/rates and resources available to obtain them.
List of Acronyms

• CDA – Confidentiality (Non-Disclosure) Agreement
• CPT – Clinical Procedural Terminology
• CRF – Clinical Research Form
• CRIS – Clinical Research Initiation Services (now ORA)
• CRO – Clinical Research Organization
• CTO – Clinical Trials Office
• CTRS – Clinical Translational Research Site (former CRC)
• F&A – Facilities and Administrative (fka overhead)
• FB- Fringe Benefits
• ICF – Informed Consent Form
• IND – Investigational New Drug
• IRB – Institutional Review Board
• JHS – Jackson Health Systems
• MCA – Medicare Coverage Analysis (aka Billing Grid)
• MRA – Medical Research Administration (now ORA)
• MTA – Material Transfer Agreement
• NIH – National Institute of Health
• ORA – Office of Research Administration
• PCRF-L – Proposal/Contracting Routing Form (Long)
• PI – Principal Investigator
• PK – PharmacoKinetics
• SAE – Serious Adverse Event
ORA General Responsibilities and Contacts

- Reviews, approves and submits proposals for research funding
- Negotiates and executes research agreements, MTAs and CDAs
- Facilitates negotiations and execution of data use agreements
- Performs Medicare Coverage Analysis (MCA) for all clinical trials
- Provides research pricing for clinical procedures performed at UM non-research facilities for budgeting purposes
- Manages awards and performs financial reporting and compliance functions (Post-Award functions)

Contact Us (Pre-Award):
- Applications, Federally-supported agreements and inquiries: MRA@med.miami.edu
- Non-Federally supported agreements and inquiries: CRIS@med.miami.edu
- For more information and contacts visit us at: http://ora.miami.edu/
Research Proposal Submission and Budgeting Specifics
PI/Study Team/Research Support (certain submissions)

- Builds complete budget to include:
  - personnel costs (percentage of effort)
  - costs of clinical procedures and services to be covered by the external funding source (research patient care costs)
  - materials and supplies
  - equipment
  - travel
  - subjects’ compensation
  - services by outsiders (including JHS), etc.
- Provides accurate and complete budget justification
- Uses institutional resources (F&A and FB rates, forms, etc.): http://ora.miami.edu/forms-and-rates/
Office of Research Administration (ORA)

- Provides research pricing for clinical procedures performed at UM non-research facilities (research patient care costs)
- Provides guidance on billing status of clinical procedures (grant vs. Medicare/Third Party payers) if desired and deadline-permitting
- Reviews complete budget (deadline-permitting). See http://ora.miami.edu/assets/pdf/ora-policies/application-deadline.pdf
- Submits application
Governmentally-Funded Clinical Research and Clinical Trial Budget
Research with human subjects that is:

1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. It includes: (a) mechanisms of human disease, (b), therapeutic interventions, (c) clinical trials, or (d) development of new technologies.

2) Epidemiological and behavioral studies.

3) Outcomes research and health services research

Studies falling under 45 CFR 46.101(b) (4) (Exemption 4) are not considered clinical research by this definition.
A research study\(^1\) in which one or more human subjects\(^2\) are prospectively assigned\(^3\) to one or more interventions\(^4\) (which may include placebo or other control) to evaluate the effects of those interventions **on health-related biomedical or behavioral outcomes**\(^5\).

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1, 2 See Common Rule definitions at 45 CFR 46.102(d, f)

3 The term “prospectively assigned” refers to a pre-defined process specified in an approved protocol that stipulates the assignment of research subjects (individually or in clusters) to one or more arms of a clinical trial.

4 An “intervention” is defined as a manipulation of the subject or subject’s environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Examples include: drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and, diagnostic strategies.

5 A “health-related biomedical or behavioral outcome” is defined as the pre-specified goal(s) or condition(s) that reflect the effect of one or more interventions on human subjects’ biomedical or behavioral status or quality of life. Examples include: positive or negative changes to physiological or biological parameters (e.g., improvement of lung capacity, gene expression); positive or negative changes to psychological or neurodevelopmental parameters (e.g., mood management intervention for smokers; reading comprehension and /or information retention); positive or negative changes to disease processes; positive or negative changes to health-related behaviors; and, positive or negative changes to quality of life.
NIH Definition of Research Patient Care Costs

The costs of routine and ancillary services provided by hospitals to individuals participating in research programs.

- **Routine services** are the regular room services, minor medical and surgical supplies, and the use of equipment and facilities, for which a separate charge is not customary made.

- **Ancillary services** are Those special services for which charges are customarily made in addition to routine services, e.g., x-ray, operating room, laboratory, pharmacy, blood bank, and pathology.
Research patient care costs do not include:

- Items of personal expense reimbursement (e.g., patient travel or subsistence, consulting physician fees, etc.)
- Costs of ancillary tests performed in facilities outside the hospital on a fee-for-service basis (e.g., in an independent, privately owned laboratory) or laboratory tests performed at a medical school/university not associated with a hospital routine or ancillary service
- Recruitment or retention fees, the data management or statistical analysis of clinical research results
Budgeting for Governmentally-Funded Clinical Trials

- PI must have a minimum of 1% effort on the budget. Effort covers all PI’s work, including professional fees for clinical services and procedures.
- Clinical procedures are to be priced at the research rate for Governmentally-funded research (obtain from ORA)
- General administrative expenses should not be included as direct costs on the budget (some exceptions exist)
- Use current applicable fringe benefit rates and F&A rate
- Equipment valued at >$2,500, patient care costs (inpatient & outpatient), participant support costs and some other costs are not subject to F&A costs.
What costs are not subject to F&A costs on a Governmentally-funded project?

- **Patient Care Costs** – Are costs of routine and ancillary hospital services provided to individuals participating in a research program.

- **Equipment** - Is a stand-alone piece, valued at $2,500 or more, which has a useful life for more than a year at the time of acquisition. Freight and installation charges, if any, are considered part of the acquisition cost.

- **Subcontracts** - The portion of each subcontract in excess of $25,000. For example: UM will issue two subcontracts each for $100,000. F&A is charged to $25,000 of each of the subcontracts.

- **Student Tuition Remission, Scholarships and Fellowships, Rental costs and Participant Support Costs** (support for UM employees attending certain research events).
Contracts for Clinical Research and Clinical Trials
(no previous proposal submission)
Budgeting Specifics
Roles and Responsibilities
Contracts (no previous proposal submission)

**PI/Study Team/Department**

- Reviews sponsor’s budget for feasibility: technical and personnel resources, personnel costs and study-specific items
- Provides information about costs of non-procedural items, including personnel time and study-specific items via PCRF-L
- Obtains pricing from special units performing study services (CTRS, research units/labs, outside providers, etc.)
- If applicable, completes JHS CTO application and Study Calendar and makes them available for JHS CTO review
- Works with ORA on review and approval of MCA and budget, answers questions, including the ones regarding specifics of clinical procedures, and approves final budget.
PCRF-L – Budget Information Section
Non-Governmental

Used when there is a financial transaction involving new money
For clinical research/clinical trials section below should be completed with as much details as possible.
If desired, separate non-procedural detailed internal budget may be submitted.

<table>
<thead>
<tr>
<th>Budget Information, Including Faculty &amp; Study Personnel Time And Study -Specific Items</th>
</tr>
</thead>
<tbody>
<tr>
<td>Please estimate the average administrative time, per visit, that study personnel will spend per patient. Examples of administrative time include recruiting, administration of ICF and questionnaires, and any other assessments generally not billable (no CPT code). It does not include time for performing billable clinical procedures such as Physical Exam, ECG, Vital Signs, CT, etc. Please do not account for time more than once by including it in multiple categories.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PI:</th>
<th>Study Coordinator:</th>
<th>Nurse:</th>
<th>Biostatistician:</th>
<th>Other Position Title:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Estimate of Total Start-Up Costs For Department (Exclusive of F&amp;A, CRIS, Pharmacy, IRB/Compliance and JHS Fees):</th>
<th>Other Position Est. Time:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Does ICF or Other Document Require Translation?</th>
<th>Into How Many Languages?</th>
<th>Provide Per Word Translation Quote, If Available:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>What is The Expected Ratio of Screen Failures to Enrolled Patients?</th>
<th>In Addition to Start-Up, What Amount of Advanced Payment is Required, If Any?</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Average Time Anticipated Performing The Following Tasks, Hours (Blended PI/Coordinator Time, If Applicable)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>SAE Reports (Each):</th>
<th>Re-Consenting (Each):</th>
<th>Monitor/FDA Visits (Each):</th>
<th>IRB Submissions (e.g., Amendments, Renewals):</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Average Dollar Amount Anticipated For This Project For The Following Items, If Applicable</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Travel:</th>
<th>Trainings:</th>
<th>Recruiting/Advertising:</th>
<th>Equipment/Supplies:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Other Costs (List):</th>
<th>Estimated Other Costs:</th>
</tr>
</thead>
</table>

http://ora.miami.edu/_assets/pdf/ora-forms/pcrf-l.pdf
Click on Forms and Rates from ORA Home Page
# PCRF-L Budget Summary Section Non-Governmental

<table>
<thead>
<tr>
<th>Budget Summary (Details Attached)</th>
<th>1st Year</th>
<th>2nd Year</th>
<th>3rd Year</th>
<th>4th Year</th>
<th>5th Year</th>
<th>Total (All Years)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Direct Costs - Subject to Facilities &amp; Admin. Rate:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Direct Costs - Not Subject to Facilities &amp; Admin. Rate:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. F&amp;A Costs: (enter as decimal, e.g., .53)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F &amp; A Rate YR 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F &amp; A Rate YR 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F &amp; A Rate YR 3-5</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. F&amp;A Costs Cumulative</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Total Agency Funds Requested:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. UM Cost Sharing/Matching Funds Included?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Total Project Costs (Lines 5 + 6):</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

**UNIVERSITY OF MIAMI**
Budget is based on the sponsor’s offer or the budget the PI deems sufficient, whichever is greater.
PCRF-L Budget Summary
Non-Governmental

Direct Costs  Not Subject to F & A

- IRB Fees (any IRB)
- Compliance Fee
- CRIS Fee
Office of Research Administration (ORA)

- Performs Medicare Coverage Analysis (MCA) to determine parties financially responsible for items and services listed
- Prices clinical procedures at research rates based on funding source (not a party to the agreement), CPT codes (accurate procedures description is important) and location of service
- Ensures that all institutional costs are accounted for
- Collaborates with JHS and UMH in budget development
- Reviews, updates and negotiates budget with the sponsor to ensure that all applicable expenses are covered
-Executes the contract (containing budget)
PI Portal was created to provide a view of ongoing contracts and budget negotiations.

The Portal is accessed via the Research Reporting System (RRS). For more information please email StrategicInitiatives@miami.edu
# Medicare Coverage Analysis (MCA)

## Contracts (no previous proposal submission)

<table>
<thead>
<tr>
<th>Items and Services</th>
<th>Screening</th>
<th>Cycle 1 of 21-Day Regimen</th>
<th>Cycle 2 of 21-Day Regimen</th>
<th>End of Treatment</th>
<th>Location of Service</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Within 21 days of First Dose</td>
<td>Day 1</td>
<td>Day 4</td>
<td>Day 8</td>
<td>Day 11</td>
<td>Day 1</td>
</tr>
<tr>
<td>Informed consent</td>
<td>NB</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Not a billable item.</td>
</tr>
<tr>
<td>Physical examinations</td>
<td>M^o</td>
<td>M</td>
<td>M</td>
<td>M</td>
<td>M</td>
<td>M</td>
</tr>
<tr>
<td>Symptom-directed examinations</td>
<td>M^o</td>
<td>M</td>
<td>M</td>
<td>M</td>
<td>M</td>
<td>M</td>
</tr>
<tr>
<td>Phlebotomy</td>
<td>M</td>
<td>M</td>
<td>M</td>
<td>M</td>
<td>M</td>
<td>M</td>
</tr>
<tr>
<td>PT/PTT or INR</td>
<td>M</td>
<td>M</td>
<td>M</td>
<td>M</td>
<td>M</td>
<td>M</td>
</tr>
<tr>
<td>Hematology</td>
<td>S^a</td>
<td>M</td>
<td>M</td>
<td>M</td>
<td>M</td>
<td>M</td>
</tr>
<tr>
<td>Serum Chemistry: comprehensive panel</td>
<td>S^a</td>
<td>M</td>
<td>M</td>
<td>M</td>
<td>M</td>
<td>M</td>
</tr>
<tr>
<td>Urinalysis with microscopic exam</td>
<td>M^o</td>
<td>M</td>
<td>M</td>
<td>M</td>
<td>M</td>
<td>M</td>
</tr>
<tr>
<td>12-Lead EKG</td>
<td>S^a</td>
<td>M</td>
<td>M</td>
<td>M</td>
<td>M</td>
<td>M</td>
</tr>
<tr>
<td>Gemcitabine/Carboplatin with administration</td>
<td>M</td>
<td>M</td>
<td>M</td>
<td>M</td>
<td>M</td>
<td>M</td>
</tr>
<tr>
<td>Study drug</td>
<td>S</td>
<td>S</td>
<td>S</td>
<td>S</td>
<td>S</td>
<td>S</td>
</tr>
<tr>
<td>Administration of a study drug</td>
<td>S</td>
<td>S</td>
<td>S</td>
<td>S</td>
<td>S</td>
<td>S</td>
</tr>
<tr>
<td>Radiologic tumor assessment/clinical staging by scans (CT, MRI, FDG-PET) with mandatory inclusion of chest, abdomen, and pelvis</td>
<td>M (within 21 days)</td>
<td>M/S (post cycle)</td>
<td>M/S (post cycle)</td>
<td>M/S (post cycle)</td>
<td>M/S (post cycle)</td>
<td>M/S (post cycle)</td>
</tr>
<tr>
<td>Pregnancy test (serum or urine)</td>
<td>S</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Billable to Medicare as medically reasonable and necessary to monitor patient disease and treatment effects per Medicare Benefit Policy Manual, Ch. 15, Sec. 30.1 and CMS NCD 310.1.</td>
</tr>
<tr>
<td>Adverse events</td>
<td>NB</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Not a billable item.</td>
</tr>
<tr>
<td>Survival and treatment status</td>
<td>NB</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Not a billable item.</td>
</tr>
</tbody>
</table>
How to review and interpret MCA

- MCA determines which party is financially responsible for each item and service required by the Protocol and serves as a base for a fiscally sound budget and research billing compliance affecting study’s finances and subjects’ billing - should be reviewed by PI before budget negotiations.

- Billing Grid: clinical procedures must be correctly described to account for all costs, billing determinations and procedures’ locations accurate.

- Read comments describing how billing determinations were made and provide feedback on your agreement or disagreement with them.

- Finalized MCA has to be signed by PI and will be available in Velos.

- NEW! To simplify reconciliation of budgets with MCA ORA is implementing a change for billing determinations involving non-clinical items: instead of “NB” such items will be marked “S” if sponsor is financially responsible for them. Implementation date is February 13 for all new MCAs.
Non-Governmentally Funded Clinical Trial Budget
Specifics of Non-Governmental-Funded Clinical Trial Budget

- Budgets are in various formats driven by sponsor
- Most typical budgets consist of per subject/per visit amount and various invoiceable items, often a mix of invoiceable clinical procedures and administrative and institutional costs
- Per subject/per visit amount consists of clinical procedures and personnel-related costs, not always clearly separated
- Not all budgets clearly show direct costs and F&A costs
- Line items on detailed budgets not necessarily reflect specific costs of clinical procedures and non-clinical items. Look for the total per subject amount as a guidance
- Payment terms for invoiceable items are important. Unless specifically stated, these items are not paid automatically.
Specifics of Non-Governmentally Funded Clinical Trial Budget

• ORA develops budget comprised of clinical costs at non-Governmental research rates (based on CPT codes and service location), personnel, study-specific and institutional costs

• Costs of inpatient and investigational procedures are obtained from the hospitals where procedures are taking place

• Total of this budget is reflected on the sponsor’s budget template, while individual line items’ values may not necessarily reflect UM individual items costs

• If study uses external IRB (but not sponsor’s Central IRB), IRB fees are incorporated into budget by reference. UM HSRO is handling external IRB invoices and sponsor’s payments.

• Sponsors usually pay Central IRBs of their choice directly.
Hidden Costs in Clinical Trials

- Submission of Amendments and Annual Reports to IRB.
- Anticipated high rate of screen fails.
- Equipment or supplies not provided by the sponsor.
- Translation Costs.
- Extensive Number of SAE and IND reports.
- Lodging, meals, transportation costs for subjects.
- Pre-Enrollment Activities.
- Expense for Offsite Storage.
- Non Standard Research Pharmacy Expenses.
- Lengthy visits and personnel time beyond “standard” visit.
- Site Initiation Visit.
- Site Close-Out Visit.
- Study Monitoring (on-site and remote) and FDA audits.
- Required extensive training of personnel.
Intramural Research and Proposals for Non-Governmentally Funded Clinical Research and Clinical Trials
Roles and Responsibilities
Intramural Research and Non-Governmentally Funded Proposals

PI/Study Team/Research Support

• Builds complete budget to include:
  – personnel costs
  – costs of clinical procedures to be covered by internal or external funding source at applicable research rates (industry vs. non-industry)
  – equipment, materials and supplies, travel
  – subjects’ compensation
  – services by outsiders (including JHS), etc.
  – institutional costs

• Uses institutional resources (F&A and FB rates, budget aid tools):
  http://ora.miami.edu/forms-and-rates/
  http://ora.miami.edu/about-ora/Clinical-Research/contracting-and-budgeting/
Office of Research Administration (ORA)

- Provides research pricing for clinical procedures performed at UM non-research facilities (research patient care costs)
- Provides guidance on billing status of clinical procedures (funding source vs. Medicare/Third Party payers), if desired, to assist with determination of costs to be covered by a funding source and ensure research billing compliance.
- Reviews complete budget and submits proposal to external funding source when applicable
- Completes full Medicare Coverage analysis once study is up and running.
Budgeting for Non-Governmentally Funded Clinical Trial Proposal or Internal Grant

Build the Complete Budget
- Personnel, clinical procedures, supplies, equipment, subjects’ compensation, service by outsiders, etc.
- Institutional costs (i.e., IRB, CRIS, and Pharmacy fees)

Apply F & A Costs
- 29% for Industry-supported clinical trials
- 53.5% for non-Industry supported clinical trials and research. (Is this current rate? Does sponsor limit F&A?)

Items Not Subject to F&A Costs
- IRB fees, CRIS fee, Compliance fee in industry-supported clinical trials
Q & A

Thank You!