Developing Study Budgets in Clinical Research

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Office of Research Administration (ORA), Pre-Award
(fka Clinical Research Initiation Services “CRIS”)

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• Office of Research Administration (ORA): Part of Finance and Treasury.
• ORA approves and submits applications for research funding, negotiates and executes research, material transfer and confidentiality agreements, performs Medicare coverage analysis (MCA) for clinical trials, manages awards, and performs certain reporting and compliance functions.
• For more information please visit our website: http://www.miami.edu/finance/index.php/ora_homepage/
Roles and Responsibilities in Budget Development

• **PI and study team**: Responsible for preparing budget including personnel time, effort and costs of items and services specific to the study.

• **ORA**: Responsible for preparing billing grid (MCA), clinical procedures costs and other institutional costs portion of budget.

• **Proposal submission**: ORA assists with clinical procedures pricing as needed. PI and study team (with MedReps assistance) prepare the final budget and submit to ORA.

• **Contracting with third parties**: ORA reviews and negotiates budgets and execute agreements.

It is a joint effort!
**Budget Information, Including Faculty & Study Personnel Time**

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.

<table>
<thead>
<tr>
<th>Role</th>
<th>Quantity</th>
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</thead>
<tbody>
<tr>
<td>PI</td>
<td></td>
</tr>
<tr>
<td>Study Coordinator</td>
<td></td>
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<tr>
<td>Nurse</td>
<td></td>
</tr>
<tr>
<td>Biostatistician</td>
<td></td>
</tr>
<tr>
<td>Other Position</td>
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**Estimate of Total Start-Up Costs For Department (Exclusive of CRIS, Pharmacy, IRB/Compliance and JHS Fees):**

<table>
<thead>
<tr>
<th>Category</th>
<th>Quantity</th>
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<tbody>
<tr>
<td>Other Estimated Time</td>
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**Does ICF or Other Document Require Translation?**

- [ ] Yes
- [ ] No

Provide Per Word Translation Quote, If Available

**What is The Expected Ratio of Screen Failures to Enrolled Patients?**

**In Addition to Start-Up, What Amount of Advanced Payment is Required, If Any?**

**Average Time Anticipated Performing The Following Tasks**

<table>
<thead>
<tr>
<th>Task</th>
<th>Quantity</th>
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<tbody>
<tr>
<td>SAE Reports (Each)</td>
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</tr>
<tr>
<td>IND Safety Reports (Each)</td>
<td></td>
</tr>
<tr>
<td>Monitor/FDA Visits (Hours Per Day)</td>
<td></td>
</tr>
<tr>
<td>IRB Submission (e.g., Amendments)</td>
<td></td>
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</tbody>
</table>

**Average Dollar Amount Anticipated For This Project For The Following Items, If Applicable**

<table>
<thead>
<tr>
<th>Item</th>
<th>Cost</th>
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</thead>
<tbody>
<tr>
<td>Travel</td>
<td></td>
</tr>
<tr>
<td>Trainings</td>
<td></td>
</tr>
<tr>
<td>Recruiting/Advertising</td>
<td></td>
</tr>
<tr>
<td>Equipment/Supplies</td>
<td></td>
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</tbody>
</table>

Describe Other Costs

<table>
<thead>
<tr>
<th>Estimated Other Cost</th>
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</table>
NIH defines Research Patient Care Costs as following:

- The costs of routine and ancillary services provided by hospitals to individuals, including patients and volunteers, participating in research.
- Routine services are the regular room services, minor medical and surgical supplies, and the use of equipment and facilities.
- Ancillary services are services charged 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, such as patient travel, consulting physician fees, etc.
- Costs of ancillary tests done outside the hospital on a fee-for-service basis (e.g., in an independent laboratory, such as Quest) or laboratory tests performed at a medical school or university not associated with a hospital routine or ancillary service, such as tests performed at the research laboratories.
- Recruitment or retention fees or the data management or statistical analysis of clinical research results.
Budgeting for Federally-funded Clinical Trials

- Principal Investigator must have at least 1% effort on the budget or department is required to cost-share an effort (unless announcement for funding states otherwise).
- Use the most current applicable F&A rate and fringe benefits rates for salaries (available on ORA website).
- Clinical procedures have to be priced at the research rate for Federally-funded research – contact ORA for pricing.
- General administrative expenses should not be included as direct costs on the budget. Some exceptions may apply.
- Equipment valued $2,500 and more and patient care costs (inpatient and outpatient) are not a subject to Facility and Administrative costs (overhead).
Tips on Developing Budgets

• Carefully review study Protocol and other materials and conduct financial feasibility review as it applies to personnel time and costs of study-specific items.

• Have justification and documentation available to support personnel costs and costs of study-specific items.

• If use of Research Pharmacy, CRC, research or outside laboratory or other research facility is anticipated, contact them directly to discuss feasibility and obtain costs.

• If use of JHS facilities is anticipated, complete and submit JHS CTO application and Study Calendar and submit study to IRB to enable JHS CTO review.
Hidden Costs in Clinical Trials
Budgets

• Pre-enrollment activities: documents review, IRB submission, trainings, meetings, advertisement, site initiation, subjects identification and recruitment, screen fails.

• Research Pharmacy expenses, especially if there are specific requirements regarding the study article.

• Study monitoring and CRF queries by sponsor or CRO; audits, including FDA audits.

• Extensive number of SAE and IND reports.

• High volume and complexity of CRFs. Lengthy questionnaires.

• Submission of amendments and annual reports to IRB; subjects re-consenting due to amendments.
Hidden Costs in Clinical Trials Budgets (continued)

- Lengthy collections of PK samples and prolonged study visits.
- Subjects transportation/lodging expenses if recruiting from an extended geographic area.
- Equipment not provided by sponsor.
- ICF translation, especially if more than one language.
- Archiving expenses, especially if high volume of study documents is required to be stored off-site for a prolonged period of time.
How to reach us?

• Applications, Federally-funded research agreements and inquiries: MRA@med.miami.edu

• Non-Federally funded research agreements and inquiries: CRIS@med.miami.edu

More information and forms (including UM rates and information, Proposal Transmittal Form, Guarantee Form, JHS CTO forms and Pharmaceutical Close-Out Form):
http://www.miami.edu/finance/index.php/ora_homepage/

THANK YOU!