Effective Fiscal Management of Industry Clinical Trials

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Agenda

• Team organization & resources
• Challenges managing clinical trials
• CHLA’s approach
• Insight from Huron’s experience
• Questions
Contracts & Clinical Research Team

- Most administrative functions centralized here

- Pre-Award
  - Negotiate all research agreements, inc. CTAs
  - Negotiate clinical trial budgets
  - Coverage analysis (outsourced)
Contracts & Clinical Research Team

• Post-Award
  • Financial maintenance
    • Project setup
    • Invoicing
    • A/R, including aged A/R
    • Monitoring accounts for deficits

• Clinical trial management system administrators

• Study subject payment system management

• Final account close-out
  • Payroll reconciliation
Fiscal Management of Clinical Trials

• It’s hard!

• GAAP/GASB rules state that costs benefitting the project should be assigned to that specific project, but...
Why Is This So Challenging?

• Research coordinator effort is typically budgeted on per visit basis or per procedure basis, not by CRC’s percentage of FTE

• Disconnect between departmental budget manager and study team
Additional Challenges

- Institutions usually have residual funds policies that allow PIs to “keep” unexpended funds in discretionary accounts.

- PIs leave accounts open after the study ends and spend out the funds.
Additional Challenges

- Unless an institution has a CTMS, study team must be trusted to invoice appropriately

- Payment reconciliation
  - Internal issues
    - Milestone (CRF) payments may not have A/R offset
    - Payments not correctly coded
  - External issues
    - Payment amounts aren’t 1:1 with invoices
    - Sponsor holdbacks

- Any other issues?
CHLA’s Approach (easy things)

• Streamlined negotiations
  • Used more master agreements
  • Developed a research charge master

• Streamlined invoicing
  • Centrally generate start-up invoice at account setup
  • Developed budget specific templates for CRCs
CHLA’s Approach (harder things)

• Moved all post-award functions to CCR team
  • Partnered with Post-Award team; created 1 year transition plan
    • CCR knows contract, budget, and study team
  • All invoicing
  • A/R management
CHLA’s Approach (hardest thing)

- Developed account closeout/expense analysis process
  - Reconcile expired IRB approvals with open project accounts
- Compare enrollment activity with contract budget
  - Has appropriate payroll expenses been applied to the account?
Close-out Analysis Tool

<table>
<thead>
<tr>
<th>Total Payments Received</th>
<th># of Patients Enrolled</th>
<th>Enrollment Breakdown</th>
<th>PI Name: Protocol 1234</th>
</tr>
</thead>
<tbody>
<tr>
<td>Auto Payment (04/26/16)/INV 01</td>
<td>$2,337.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Auto Payment (05/16/2016)/INV 02</td>
<td>$5,996.00</td>
<td></td>
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</tr>
<tr>
<td>Auto Payment (06/23/16)/INV 003</td>
<td>$13,664.00</td>
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<td></td>
</tr>
<tr>
<td>Auto Payment (07/12/16)/INV 004</td>
<td>$11,874.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Auto Payment (08/15/16)/INV 05 &amp; 06</td>
<td>$14,850.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Auto Payment (09/11/16)/INV 00</td>
<td>$7,916.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Auto Payment (10/07/16)/INV 08</td>
<td>$5,000.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Auto Payment (12/13/16)/INV 09</td>
<td>$17,539.50</td>
<td>4 Subjects up to week 16, ET, FU</td>
<td></td>
</tr>
<tr>
<td>Auto Payment (01/09/17)/INV 10 &amp; 11</td>
<td>$34,821.28</td>
<td>1 Subject up to week 8, ET, FU</td>
<td></td>
</tr>
<tr>
<td>Auto Payment (08/25/17)/INV 12</td>
<td>$1,080.00</td>
<td>1 Subject up to week 16, ET</td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>$110,578.38</strong></td>
<td><strong>Per Patient Total $30,422.00</strong></td>
<td><strong>Sponsor: Sponsor Name</strong></td>
</tr>
</tbody>
</table>

**Budget to Actual Comparison**

**ACTUAL**

<table>
<thead>
<tr>
<th>Payroll Expenses</th>
<th>Dollars</th>
</tr>
</thead>
<tbody>
<tr>
<td>PI Wages:</td>
<td>$0.00</td>
</tr>
<tr>
<td>SC Wages:</td>
<td>$18,454.15</td>
</tr>
<tr>
<td>RN Wages:</td>
<td>$0.00</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>$18,454.15</strong></td>
</tr>
</tbody>
</table>

**BUDGET APPLIED**

<table>
<thead>
<tr>
<th>Payroll Expenses</th>
<th>Dollars</th>
</tr>
</thead>
<tbody>
<tr>
<td>PI Wages:</td>
<td>$14,279.20</td>
</tr>
<tr>
<td>SC Wages*:</td>
<td>$20,265.25</td>
</tr>
<tr>
<td>RN Wages:</td>
<td>$0.00</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>$34,544.45</strong></td>
</tr>
</tbody>
</table>

**VARIANCE**

<table>
<thead>
<tr>
<th></th>
<th>Dollars</th>
</tr>
</thead>
<tbody>
<tr>
<td>Payments Received</td>
<td>$110,578.38</td>
</tr>
<tr>
<td>Expenses Applied</td>
<td>-$47,258.20</td>
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<tr>
<td><strong>Subtotal</strong></td>
<td><strong>$63,320.18</strong></td>
</tr>
<tr>
<td>Time &amp; Effort Not Expensed</td>
<td>-$16,090.30</td>
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<tr>
<td>Balance</td>
<td>$47,229.88</td>
</tr>
<tr>
<td>Percentage</td>
<td>42.71%</td>
</tr>
<tr>
<td>IDC (35%)</td>
<td>-$12,244.78</td>
</tr>
<tr>
<td>Amount Available For Transfer</td>
<td>$34,985.10</td>
</tr>
</tbody>
</table>

* Coordinator time reduced by 50% to more closely account for actual costs.
Implementation

- Due diligence
  - Partnered with General Accounting to develop close-out process to ensure appropriate handling
  - Review all applicable projects for a specific PI so deficits can be resolved against balances
  - Collect full IDC on total revenue received, even if waiver or reduction was approved at award
Implementation

• Communication plan
  • Recognized these changes would be a culture change, esp close-out process
  • Socialized in advance by announcing/discussing at many various meetings
Implementation

• Concierge service
  • Slow, thoughtful implementation

• Flexible and responsive to feedback

• Work directly with division administrators (budget decision-makers) to review and adjudicate accounts based on analysis

• Division decides whether to subsidize PI with salary support
Results

- Decreased average turnaround time for CTAs ~50% (current average = ~75 calendar days)
- More than doubled clinical research revenue in two FYs
- Collected over $550k in aged A/R
- Resolved $1.95M in “found” money that was in the wrong account or improperly coded
- Close-out has yielded over $100k in uncharged salary and IDC in Q1-2 of 2019
Change Your Mindset – Change Your Results

Big Picture Point of View: *Stronger Together*

- Create Standardization
  - Pricing Approach
    - Complexity Based
    - Therapeutic Based
  - Document Support

- Find Balance
  - Define Expectations
  - Establish Thresholds
Change Your Mindset – Change Your Results

Big Picture Point of View: Don’t Subsidize For-Profit Industry Research

• You took the time to budget, verify it’s working
  • Compare Budget to Actuals
  • Review expenses

• “You earned it, collect it”
  • Verify receipt of start-up, closeout, and invoiceable items
  • Pick a strategy to document invoiceable needs and implement it with all new trials
Change Your Mindset – Change Your Results

Big Picture Point of View: *Use Failure to Create Innovation*

- Failure is Part of the Change Process
  - Remain Open
  - Make Adjustments
  - Focus on the Common Goal
Questions?

Thank you!