JCTO

Contracts Process Enhancements
Areas of Focus

• Improve turnaround times
• Eliminate non-essential steps
• Streamline administration and management
• Strengthen controls and monitoring
• Develop standard operating procedures
Areas of Improvement

- Removal of the ERF from JCTO Contracts process
- Contracting Performance
- Contracts Weekly Investigator Report Enhancement
- Contracts Intake Consolidation
- Contract Negotiation Uniformity
Effective July 1, 2015

Removal of the ERF from JCTO Contracts process
# Electronic Routing Form Changes

<table>
<thead>
<tr>
<th>Category</th>
<th>Current Workflow</th>
<th>New Workflow</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conflicts Indicator</td>
<td>Answer y/n on ERF</td>
<td>No longer required; handled through IRB</td>
</tr>
<tr>
<td>HRBAF</td>
<td>Attachment within ERF</td>
<td>No longer required; *Must still be reviewed by Department Compliance Liaisons and submitted to the IRB and Billing Compliance Office</td>
</tr>
<tr>
<td>Chair/Desigee Approval</td>
<td>ERF Routing</td>
<td>No longer required; handled through the IRB protocol approval process</td>
</tr>
<tr>
<td>Final Budget</td>
<td>Attachment within ERF</td>
<td>New Central Financial Review Process</td>
</tr>
</tbody>
</table>
New Central Financial Review Process

PROCESS CHANGE: Effective July 1st 2015, JCTO Finance began conducting a central review of all clinical research budgets and payment terms.

BENEFIT: Ensure correct and consistent inclusion of fees, indirect cost rates, payment terms and contact information.
Financial Review Process Workflow

Study team emails JCTO Finance at JCTOFinance@med.cornell.edu the budget and payment terms for review using the Budget Submission Email template.

JCTO Finance reviews the budget and payment terms. Questions and recommendations are communicated to the study team.

JCTO Finance sends JCTO Contracts the final budget and payment terms copying the study team.
Budget and Payment Terms Financial Review

Verification of Indirect Cost Rate

- 33% Clinical Trial Agreements (Industry)
- 69.5% Service Agreements
- 69.5% All other industry sponsored research
- % Varies: Foundation studies require a written policy or public link to rate

Institutional Fees

- JCTO, CSEC, IRB, etc. (refer to: Clinical Research Administrative Fees)

Sponsor Cap on Number of Occurrences of Contracted Items

- IRB – Continuing Renewal and Amendments
- Screen-failures
- Re-consenting
- Re-screening

Payment Mechanism

- Invoice or automatic payment based on CRF completion/monitoring
- Invoice or automatic payment based on milestones
Budget and Payment Terms Financial Review

Subject Compensation

• Verify whether subject compensation is provided and appropriately included in the study budget.

Payment Withholding Amount

• Encourage minimization of withholding amount to 10% or less.

The JCTO Finance team will review other items including the following:

• Net payment terms
• Payment of wire and/or electronic transfer fees
• CRO payment and contact information

Payment Address:

• Verify the payment schedule includes the JCTO payment address and contact information on the JCTO website at: http://jcto.weill.cornell.edu/investigators/study-activation-and-conduct/institutional-information
Submission Email Template

Subject Line: Budget and Payment Terms Submission: IRB#, PI Name, Sponsor Name

Body of Email:
Attached for your review are the budget and payment terms for the following study:
IRB# :
PI Name :
Sponsor Name :
Sponsor Protocol # :

The indirect cost, verification of Hospital and Investigational Pharmacy services billable to the study are specified below.

Indirect Cost Rate:
Verification of Hospital Services Billable to the Study: Yes or No (Select One)
Verification of Investigational Pharmacy Services Billable to the Study: Yes or No (Select One)
Q&A

• **When should I submit my study budget for review?**
  – The review process must be completed prior to the execution of a contract including those contracts currently under negotiation.

• **Who should I contact for budget and payment terms assistance or guidance?**
  – If you would like assistance or guidance on budget development please contact JCTO Finance at jctofinance@med.cornell.edu
Fiscal 2014 through 2015 Q3

Contracting Performance
## Contract Throughput & Growth

<table>
<thead>
<tr>
<th>Agreement Type</th>
<th>2013</th>
<th>2014</th>
<th>% Growth</th>
<th>2015</th>
<th>% Growth</th>
<th>Grand Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Confidentiality Agreement</td>
<td>126</td>
<td>178</td>
<td>41.27%</td>
<td>241</td>
<td>35.39%</td>
<td>545</td>
</tr>
<tr>
<td>Clinical Trial Agreement</td>
<td>97</td>
<td>163</td>
<td>68.04%</td>
<td>192</td>
<td>17.79%</td>
<td>452</td>
</tr>
<tr>
<td>Amendments</td>
<td>112</td>
<td>109</td>
<td>-2.68%</td>
<td>113</td>
<td>3.67%</td>
<td>334</td>
</tr>
<tr>
<td>Other Agreements*</td>
<td>30</td>
<td>31</td>
<td>3.33%</td>
<td>46</td>
<td>48.39%</td>
<td>107</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>365</strong></td>
<td><strong>481</strong></td>
<td><strong>31.78%</strong></td>
<td><strong>592</strong></td>
<td><strong>23.08%</strong></td>
<td><strong>1438</strong></td>
</tr>
</tbody>
</table>

- Year-Over-Year growth is sizable and consistent
- CTA and CDA volumes have nearly doubled over the last two years

* Other Agreements include Material Transfer Agreements, Data Use Agreements, Registries, Master Agreements and Compassionate Use Agreements
Clinical Trial Agreements Trending
(By Fiscal Quarter)

Contributing factors:
- Created a central listserv
- Reduced the required intake documents
- Consolidated email communications for release
- Enhanced work allocation

• Filled open specialist positions
• Increased phone communications with sponsors
• Established preliminary team benchmarks
Next Steps

**Goal:** continue to reduce overall mean

**Action Items:**
- Identify causes for outlying contracts
- Eliminate non-essential steps
- Streamline negotiations through risk-based contract review
- Develop a standard escalation process
- Publish benchmark metrics for measuring performance
Target Implementation - September

Contracts Weekly Investigator Report Enhancement
Investigator Feedback

• Comments are not explanatory
• Unclear which items require investigator action
• Contracts handled by multiple teams creates confusion as to whom to contact
• Need for increased communication and requested involvement with the investigator when negotiations are delaying execution
Proposed Enhancements

• Ensure that updates in the report are consistent, clear, and descriptive
• Eliminate comments history in the report
• Enhance and standardize layout
• Provide clear contact information
• Develop a mechanism for escalation/notification for required action items
• Change workload assignments to departmental reducing points of contact
Target Completion- Fiscal Q3 2016

Contracts Intake Consolidation
Investigator Feedback

- Confusion on where contracts should be submitted
- What documents are needed per agreement type
- Lack of visibility into which team is actually handling the contract
- There are too many contract hand-offs
- Instructions for submitting contracts presupposes institutional knowledge
Enhancements in Progress

- Working group was instituted March 2015 constituting members from the JCTO, OSRA and UC to develop a consolidated contract intake process and tool with the following goals:
  - Establish routing rules for appropriate team assignment
  - Define agreement types and associated ownership
  - Review current agreement intake forms for simplification
  - Formalize a forum and process for handling contracts that do not conform to routing rules
  - Design for secure submission when off campus
  - Prepare for the integration of the tool with InfoEd
Target Completion - Ongoing

Contract Negotiation

Uniformity
Investigator Feedback

• Frustration with same contract types managed differently through different offices
• Inconsistent approach to negotiation of contract language
Enhancements in Progress

• Developing a WCMC/NYP Contracting Uniform Guidance document to define best practices
• Scheduling ongoing discussions with internal partners to discuss application of institutional guidelines
• Increased collaboration and knowledge sharing between offices