



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

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



# New Central Financial Review Process

**PROCESS CHANGE:** Effective July 1<sup>st</sup> 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](mailto: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](mailto:jctofinance@med.cornell.edu)





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Fiscal 2014 through 2015 Q3

# Contracting Performance



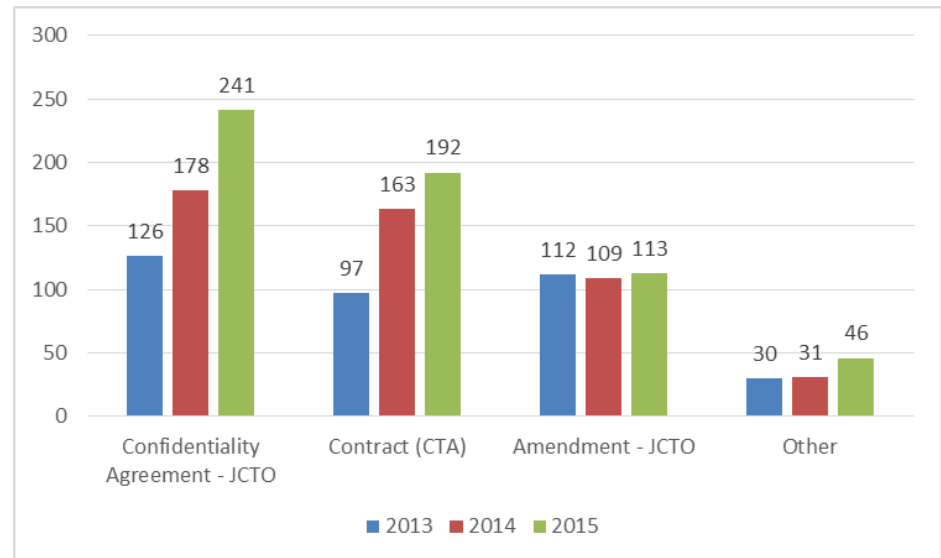
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# Contract Throughput & Growth

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

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

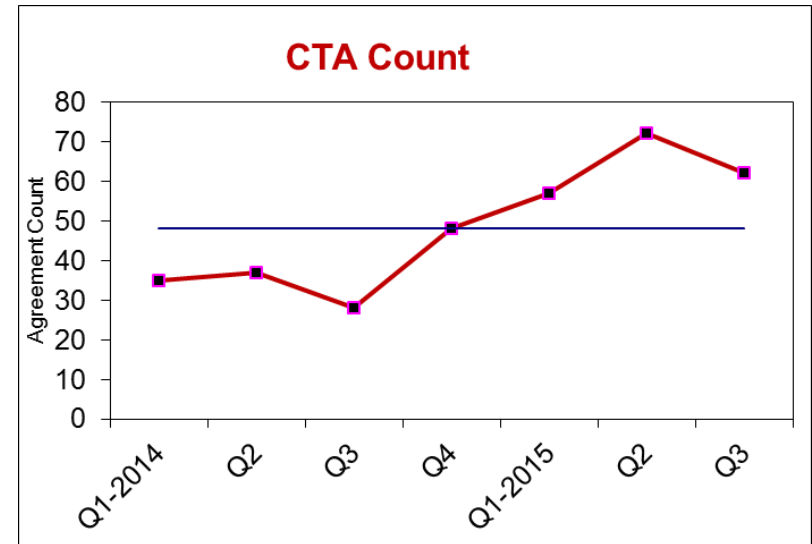
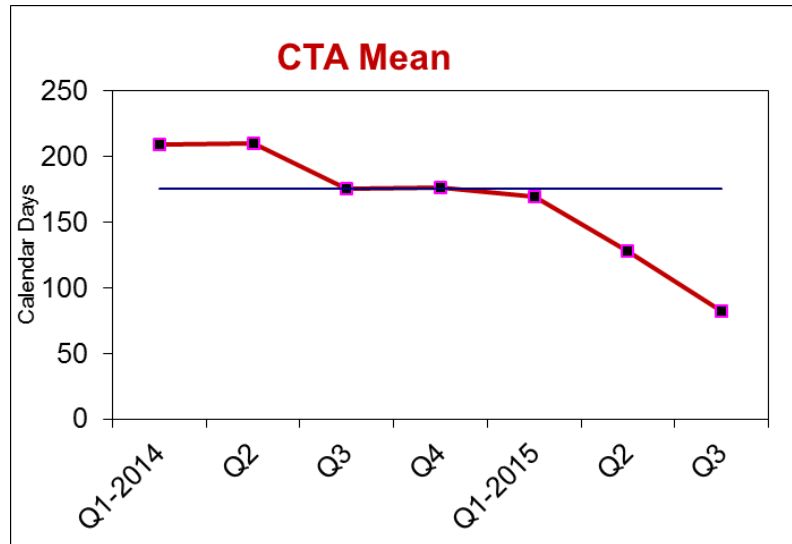


\* Other Agreements include Material Transfer Agreements, Data Use Agreements, Registries, Master Agreements and Compassionate Use Agreements



# Clinical Trial Agreements Trending

(By Fiscal Quarter)

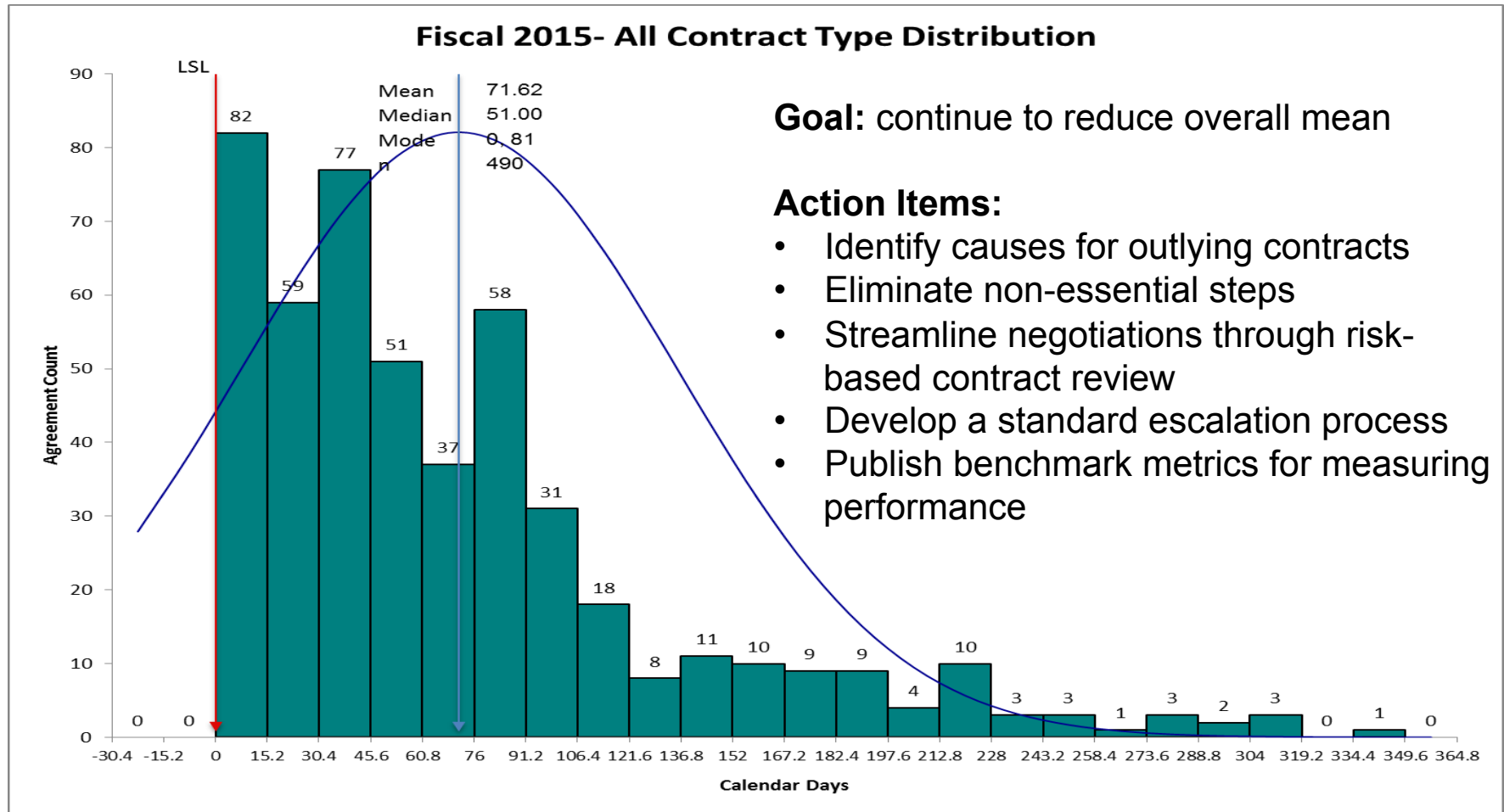


## Contributing factors:

- 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





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





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Target Completion- Fiscal Q3 2016

# Contracts Intake Consolidation



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# 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





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Target Completion- Ongoing

# Contract Negotiation Uniformity



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# 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

