Protocol Activation and Lifecycle Management (PALM)
Operational Overview

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Carly Lovelett, Assistant Director PALM
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Protocol Activation and Lifecycle Management (PALM): Purpose

1. Form a cohesive study activation & maintenance team under one accountable leader
   • 4 units – 4 separate leaderships (Reg; OnCore Support; MCA; Pre-Award)

2. Financial viability and long-term operational sustainability
   • Implement chargeback/cost recovery mechanism
   • Minimize YSM research infrastructure subsidy

3. Accelerate/Improve study activation timelines
   • Optimize performance of Investigator Services
   • Gain efficiencies through optimized workflows
Protocol Activation & Lifecycle Management (PALM)
Organizational Diagram, 2024

Sr. Associate Director, (Protocol Activation and Lifecycle Management (PALM))
R. Paz

Assistant Director, Protocol Activation and Maintenance
Carly Lovelett

Reg Activation
Ed Ramirez, Team Lead
– Muhammad Bhatti
– Megan Abbot
– Amber Hailing

Reg Maintenance
L. Bankowski, Team Lead

Intake & Activation
Chad Eriksen, Team Lead
– TBD, Intake Coordinator

OnCore Support Services
Kelly Burton, Team Lead
– Ann Pastore
– Christine Vale da Serra
– Erik McIntyre
– Ally Senkarik
– Maggie Brooks

PreAward: MCA/Budget
Nichole Brown, Team Lead
– Christine Rachev
– Betsy Vozza

Post Award - CT A/R
Pat Fontaine, AD
– Peggy Schmitzer
– TBD
– TBD
– TBD .5

CFO/Finance Director, YCCI
Anthony Gardner

Associate Director, Research Finance
Eric Borchardt

Coding & Billing
Linda O'Connor, AD
– Renee Hile-Signore
– Beth Szymanski
– Manisha Gupta
– Suzanne Ford

Clinical Research Finance Partnership

Outsource Vendors:
• Huron – MCA, Budget, Calendar (primary)
• Advarra – Calendar and financial build (primary)
• TBD – Regulatory (overflow)
PALM Services

Available Activation Services:

- Medicare Coverage Analysis (MCA)
- Budget development/negotiation
- Regulatory start-up:
  - IRB submission & ancillary committee submission (e.g., IBC)
  - Regulatory document collection
  - eReg binder set-up
  - OnCore calendar and financial builds (including ePayments)

Available Maintenance/Modification Services:

- Protocol/Budget/ICF amendment processing
  - Calendar/Financial build modifications
- Annual IRB renewals
- Reportable New Information (RNI):
  - Serious Adverse Events
  - IRB-reportable deviation
- eRegulatory binder maintenance (including IND report management, communication filing, etc.)
- Monitoring visit/closeout visit prep
YCCI Services

**Pre-award and Study Activation**
- Grant Support
  - Pre- or post-award project development
    - Grant resources
    - Letter of Support
    - Proposal budget development

**Protocol Design & Development**
- Pre- or post-award development services for Investigator Initiated Trials (IIT)
  - Study design
  - Data system set up
  - Project Management
  - Analytic support

**Study Start-up / Activation**
- Activation services available to help get projects up and running
  - IRB Submission
  - Site Regulatory Binder
  - Coverage Analysis
  - Budget build
  - OnCore Calendar Build

**Post Activation**
- Process and maintain regulatory and financial amendments
  - Project management for investigator-initiated studies
  - Data management
  - Analytic support
  - DSMB support

**Clinical Study Coordination**
- Research facilities
  - Clinical research staff (nurses and technical personnel, and coordinators)
- Research lab processing and shipping

**Quality Assurance**
- Audit preparation support
- Billing compliance reviews
- Internal monitoring

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*Yale Center for Clinical Investigation*
Process: Activation

1. Study Team Preparation & Submission:
   - Register your study in the IRES IRB system (before completing the intake form)
   - Submit YCCI intake form including the following:
     - Final protocol
     - Informed consent template
     - Draft budget
     - Lab, Pharmacy, and Investigator Brochure manuals

2. PALM Initial Processing:
   - MCA
   - Initial submissions: IRB, any ancillary committees & regulatory packet submission,
   - Budget development/review
     - Department Business Offices and OSP will be included in an initial budget review
Process Cont. & Tips

3. **PALM Study Activation:**
   - Communication with study team, sponsor, and IRB as needed until approval
   - eRegulatory binder setup
   - Budget negotiation and finalization
   - OnCore calendar and financial builds and release (contingent on fully executed CTA)

**Tips:**
- Ensure you submit to Office of Sponsored Products (OSP) for contract negotiation separately
- Submit an intake from only when you are approved as a site and have all of the necessary documents: Final protocol, draft budget & ICF, IB, any manuals (e.g., lab, pharmacy)
- If you’re not sure – ask!
### Strategies to Accelerate Timeline

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<tr>
<th>YCCI</th>
<th>Study Teams</th>
<th>Sponsors</th>
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<tr>
<td>• Have an efficient intake process.</td>
<td>• Submit intake only after study award &amp; receipt of required documents.</td>
<td>• Provide all final docs to set start date (including unlocked contract and budget templates).</td>
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<td>• Bring the appropriate parties into the process at the right times.</td>
<td>• Be timely in answering questions/ requests after submitting an intake form.</td>
<td>• Accept the Yale rate sheet and incorporate it into the draft Sponsor budget.</td>
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<td>• Provide guidance when needed.</td>
<td>• Inform YCCI of any relevant updates (e.g., upcoming protocol amendment).</td>
<td>• Have an MSA/MCTA with Yale and agree to use Yale standardized payment terms.</td>
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<td>• Collaborate and communicate across departments.</td>
<td>• Be responsive throughout the process.</td>
<td>• Be fully Sponsor paid.</td>
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**All Parties: be responsive throughout the process**
Timeline

1. Study Team Prep. & Submission
   - Day 0

2. Initial Processing
   - 60 Days

3. Study Activation
   - 120-150 Days

Goal: 120 days or less

Stretch Goal: 90 days or less
New Process Outcomes:

- **CY 24 - Activation timeline for new trials**
  - Goal: 120 days or less compared to historically: ~300 days
  - new PALM workflow proving consistent
    - 88% of trials coming in under 100 days or less

- **CY 24 - New trial submissions**
  - CY24 monthly average: 22 new trials submitted
  - Portfolio = 52% Industry; 48% = NIH/IIT/Other
Service Rates

• Rates: https://medicine.yale.edu/myysm/research/clinical-research/ycci-rates/

• There are four mandatory fees for any study that will enroll participants and has any billable events*

• Ensure to include the following if negotiating your own budget:
  • Medicare Coverage Analysis fee (where applicable)
    • Qualifying Clinical Trial (QCT) Standalone fee
  • CTMS Annual Licensing fee
  • CTMS Calendar Build
  • CTMS Financial Build

* per YSM policy mandating use of OnCore
Service Rate Setting

• USP annual rate setting

• Goal: to find the most economical way to deliver the services

• Outcomes:
  o Gained efficiencies through process reengineering
  o Cost savings per study for calendar and financial build
    ✓ Approximately $3700 per study savings – NIH/IIT
    ✓ Approximately $3900 per study savings – Industry

  o Tiered pricing levels based on trial intensity: MCA, Calendar builds
    ✓ ePayments only fee
    ✓ QCT only fee
Resources and Tools

• New YCCI website launch – mid to late July

• Budgeting tools and templates to be uploaded and announced as determined and available

• Rate justification tool for Industry Sponsors – available to DBOs now
Contact Information

Streamlined, focused communications based on topic/needs:

• Assistant Director PALM: Carly Lovelett, carly.lovelett@yale.edu
• Associate Director Research Finance, Eric Borchardt, eric.Borchardt@yale.edu
• PALM Activation Inbox: yccipalmactivation@yale.edu
  • Communication on study activation and maintenance after submission of intake form
• Coverage Analysis Inbox: coverageanalysis@yale.edu
  • Discussion of QCT/MCA needs and updates
  • Team Lead: Yvonne “Nichole” Brown, Brown, yvonne.brown@yale.edu
• OnCore Support Inbox: oncore.support@yale.edu
  • General OnCore support needs, access requests, etc.
  • Team Lead: Kelly Burton, kelly.burton@yale.edu