

# Protocol Activation and Lifecycle Management (PALM) Operational Overview

Rhonda Paz, Sr. Associate Director YCCI Carly Lovelett, Assistant Director PALM Eric Borchardt, Associate Director Clinical Research Finance

# 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

Clinical Research Finance Partnership

**CFO/Finance Director, YCCI Anthony Gardner** 



**Assistant Director, Protocol Activation and** Maintenance **Carly Lovelett** 



**Reg Maintenance** L. Bankowski, Team Lead

- Megan Abbot

Amber Hailing

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

**Research Finance Eric Borchardt** 

**Associate Director,** 



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



**Coding & Billing** Linda O'Connor, AD

- Renee Hile-Signore
- -- Beth Szymanski
- Manisha Gupta
- -- Suzanne Ford

#### **Outsource Vendors:**

**Reg Activation** 

Ed Ramirez, Team Lead

- Muhammad Bhatti

- Huron MCA; Budget; Calendar (primary)
- Advarra Calendar and financial build (primary)
- TBD Regulatory (overflow)

**PALM** Structure

**CFO** Structure





#### **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)

#### <u>Available Maintenance/Modification Services:</u>

- 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**

**Protocol Design & Grant Support** Study Start-up / **Development Activation** Pre- or -post **Activation services** Pre- or –post award award development available to help get project development services for projects up and **Pre**-award **Investigator Initiated** running Grant resources and Study Trials (IIT) • IRB Submission Letter of Support Activation Site Regulatory Binder Study design Proposal budget • Data system set up development Coverage Analysis **Budget build**  Project Management OnCore Calendar Analytic support Build

# **Post**-award and Study Maintenance

#### Clinical Study

 Process and maintain regulatory and financial amendments

**Post Activation** 

- Project management for investigatorinitiated studies
- Data management
- Analytic support
- DSMB support

### Coordination

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

#### **Quality Assurance**

- Audit preparation support
- Billing compliancereviews
- Internal monitoring



# **Process: Activation**

# 1. Study Team Preparation & Submission:

- Register your study in the <u>IRES IRB system</u> (before completing the intake form)
- Submit <u>YCCI intake form</u> 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:

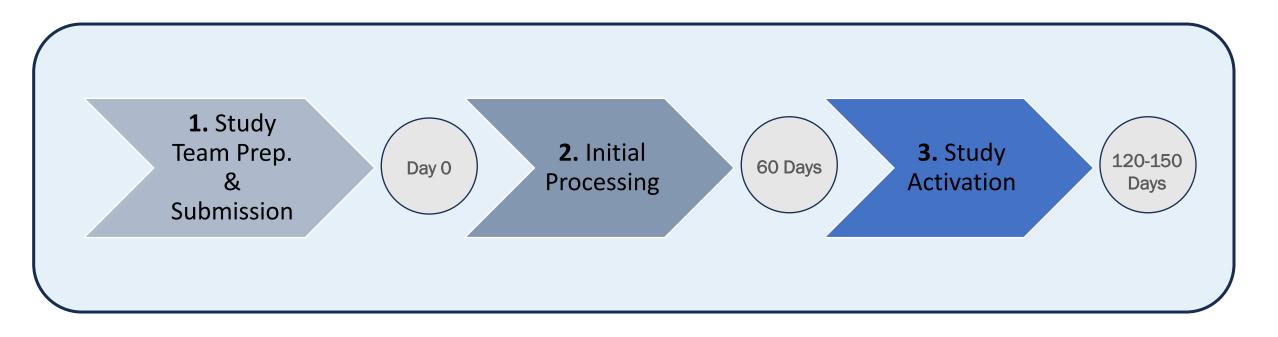
- ✓ Ensure you submit to Office of Sponsored Products (OSP) for contract negotiation separately
- ✓ Submit an intake from only when you are **approved** as a site and **have all of the necessary documents**: Final protocol, draft budget & ICF, IB, any manuals (e.g., lab, pharmacy)
- ✓ If you're not sure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

# Strategies to Accelerate Timeline

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

All Parties: be responsive throughout the process

# Timeline



Goal: 120 days or less

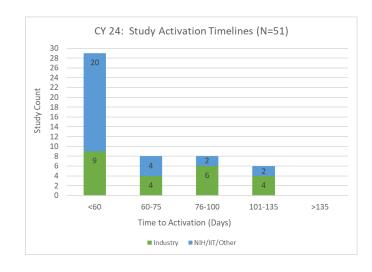
Stretch Goal: 90 days or less

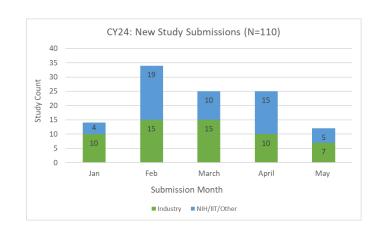
# **New Process Outcomes:**

- 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



- CY24 monthly average: 22 new trials submitted
- Portfolio = 52% Industry; 48% = NIH/IIT/Other







# Service Rates

- Rates: <a href="https://medicine.yale.edu/myysm/research/clinical-research/ycci-rates/">https://medicine.yale.edu/myysm/research/clinical-research/ycci-rates/</a>
- 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

<sup>\*</sup> 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:
  - Gained efficiencies through process reengineering
  - 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 land 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, <a href="mailto:carly.lovelett@yale.edu">carly.lovelett@yale.edu</a>
- Associate Director Research Finance, Eric Borchardt, eric.Borchardt@yale.edu
- PALM Activation Inbox: <a href="mailto:yccipalmactivation@yale.edu">yccipalmactivation@yale.edu</a>
  - 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

# Q & A

