Office of Clinical Research
Infrastructure Overview

Arash Naeim, MD PhD
Chief Medical Officer for Clinical Research
Assistant Vice Chancellor for Research
Associate Director, CTSI
Clinical Research Governance Committee

- Research Pricing & Charges
- Research Compliance
- Precision Medicine
- Research Operations
Co-location

Chief IT Strategy
Jeanne Markland

CMO-CR
Arash Naeim, MD PhD

Paul Staton
Derek Kang
Marcia Smith

Clinical Research Business Partners
Michelle McDaniel

Compliance
Polina Eshkol

IRB
Kip Kantelo

CareConnect Research
Jason Schenk

Oncore Build & Coverage Analysis
Director
Bishoy Anastasi

Clinical Research Information Systems
Director
Courtney Martin

Study Activation & Support
Director
Maggie Lindenbaum

Navigation & FDA
Director
Marlene Berro

Embedded Clinical Research & Innovation
Director, ECRI
Antonia Petrusa

CTRC
Director
TBD

Industry-Sponsored Relations
Sr. Director
Helene Orescan

Regulatory Affairs
Director
Terra Hughes

Certification and Competency
Coordinator
Sarahmay Sanchez

Ombudsperson Quality/Lean
Director
Sandy Binder

SMART Health
Director
Ramin Ramezani
Investigator & Regulatory Support

UCLA Investigator and Regulatory Support Framework

Investigator Support
- Navigation & Hub
  - Marlene Berro
- Faculty Advice & Consultation
  - Isidro Salusky
- Ombudsperson & Lean QI
  - Sandy Binder

Regulatory Support
- Scientific Review
  - John Adams
- Regulatory Affairs
  - Terra Hughes
- DSMB
  - Noah Federman

Study Activation & Support
- Maggie Lindenbaum
CROSS UNIT PROJECTS
1. Volunteers for administrative tasks
2. Volunteers as part of the clinical research team
3. Volunteers with access to systems/PHI
1. Notification of FDA Audit
2. Review of 483
3. Review of responses to FDA
Charity Policy for Clinical Research

1. Uninsured Subjects
2. Co-Pays
3. % of poverty benchmark
4. Review of eligibility
5. Coverage analysis and consent language
Use of Anonymous IDs

1. EPIC Research Record Number
2. Beaker Research Anonymity Number
3. Radiology and Lab Tests
4. Non FDA and Non CLIA Tests
5. Tracking studies and subjects
6. Proper use of CTMS and Epic
1. Integration with Oncore
2. Registration required prior to study opening in EPIC
3. Regulatory Tool to identify errors
4. Protocol/Scientific review with IRB submission
Scientific Review & Feasibility

1. IRB Notification for Cancer and Non-Cancer
2. Feasibility Check using UCREX
3. DSMB needs
4. Monitoring and Auditing
UC WIDE OPPORTUNITIES
Universal Consent For Biospecimens

1. Video and e-consenting
2. Kiosk and Mychart
3. Remnant and Dedicated tube
4. Re-contact
5. Policies and Procedures
6. Community Outreach
1. Virtual Bootcamp for Pre-IND meeting
2. SOPS for GLP Issues for Non-GLP or GLP like Studies
3. Accelerate IND submission and GCP standard
Coverage Analysis

1. Integration with IRB submission
2. Training and Certification of CA
3. Leveraging UC-wide CA resources
4. Better CRMS Integration
Contracting

1. Platform to leverage UC work product across sites
2. Multi-Institutional agreements versus Master agreements
3. Leveraging knowledge and negotiating power
4. Tie-in to Industry Relations and CROs
PROCESS IMPROVEMENT
: QUALITY & EFFICIENCY
Quality & Efficiency

• Point of Contact for issues related to clinical research infrastructure with escalation, and conflict resolution

• Identifying a Need for Policies and Procedures

• Operationalizing Policies and Procedures

Ex: Epic Access to faculty outside of Covered Entity
External Monitor access to EPIC
Charity policy for uninsured research subjects
<table>
<thead>
<tr>
<th>Item</th>
<th>UCLA</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRB (submission to 1st response*)</td>
<td>Oncore</td>
</tr>
<tr>
<td>IRB (submission to completion)</td>
<td>Oncore</td>
</tr>
<tr>
<td>CA (submission to 1st response*)</td>
<td>Oncore</td>
</tr>
<tr>
<td>CA (submission to completion)</td>
<td>Oncore</td>
</tr>
<tr>
<td>Contract (submission to 1st response)</td>
<td>Oncore</td>
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<tr>
<td>Contract (submission to completion)</td>
<td>Oncore</td>
</tr>
<tr>
<td>Total Enrollment/Planned Enrollment</td>
<td>Oncore</td>
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<tr>
<td>IRB to Contract</td>
<td>Oncore</td>
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<tr>
<td>IRB to Study Opening</td>
<td>Oncore</td>
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<tr>
<td>IRB to 1st Patient</td>
<td>Oncore</td>
</tr>
<tr>
<td>1st Patient to Study Completion</td>
<td>Oncore</td>
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</table>
# Clinical Research Dashboard Study 001

## Needs Your Attention

<table>
<thead>
<tr>
<th>Task</th>
<th>Duration</th>
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<tbody>
<tr>
<td>IRB</td>
<td>4 DAYS</td>
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<tr>
<td>Coverage Analysis</td>
<td>12 DAYS</td>
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<tr>
<td>Contracting</td>
<td>12 DAYS</td>
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## Pending / Completed / N/A

<table>
<thead>
<tr>
<th>Task</th>
<th>Status</th>
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</thead>
<tbody>
<tr>
<td>CTMS</td>
<td>Pending</td>
</tr>
<tr>
<td>EHR</td>
<td>Completed</td>
</tr>
<tr>
<td>Investigational Pharmacy</td>
<td>Pending</td>
</tr>
<tr>
<td>MTA</td>
<td>Pending</td>
</tr>
<tr>
<td>IDE</td>
<td>Pending</td>
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</table>

## Health Informatics & Analytics

- **1/1/14**

## Quick Links

- CTMS
- webIR
- EHR
- Compliance
- Clinical Trials Admin Office
### Study Data

<table>
<thead>
<tr>
<th>Study Data</th>
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<tbody>
<tr>
<td><strong>Activation Date</strong></td>
<td>01/01/2014</td>
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<tr>
<td><strong># of Sites</strong></td>
<td>06</td>
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<tr>
<td><strong>Total Patients Enrolled</strong></td>
<td>42</td>
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<tr>
<td><strong>UCLA Health System Patients Enrolled</strong></td>
<td>32</td>
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<tr>
<td><strong>External Patients Enrolled</strong></td>
<td>10</td>
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### Study Financials

<table>
<thead>
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<th>Study Financials</th>
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<tbody>
<tr>
<td><strong>Total Grant Award</strong></td>
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<tr>
<td><strong>Grant Funds Received</strong></td>
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<tr>
<td><strong>Sponsor Contract</strong></td>
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<td><strong>Sponsor Invoice</strong></td>
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<tr>
<td><strong>Sponsor Funds Received</strong></td>
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<tr>
<td><strong>Medicare Charges</strong></td>
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<tr>
<td><strong>Other Insurer Charges</strong></td>
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<tr>
<td><strong>Charges to Research Account</strong></td>
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</tbody>
</table>

### Quick Links

- CTMS
- webIRB
- EHR
- Compliance
- Clinical Trials Admin Office
AN APPROACH TO CONSIDER
Lean
• Eliminate Waste
• Increases Speed
• Improve Workflow
• Focus on Customer (Research Team)

Six Sigma
• Reduce Variation
• Improve Quality
• Optimize process
• Focus on Customer (Research Team)
Lean Council: Operations and Infrastructure

- CMO-CR or Sponsor
- IRB
- Contracting
- Coverage Analysis
- Regulatory
- Billing and Coding
- Compliance
- CTSI
- IT-CRMS
- IT-EPIC
- Education
- Evaluation
SPECIAL PROJECT
Recruitment & Retention

**Compensation**
- Specialized HR Titles for specialized clinical research staff
- A step-wise specific career and salary advancement plan

**Flexible work schedules**
- Pilot the flexible and remote work plans used in ISS in clinical research units.