Town Hall Meeting

AUGUST 25, 2023  10:00 - 11:00 AM

AGENDA

DR. RUTH O’HARA
WELCOME

RAJ PRASAD
CLINICAL RESEARCH RESOURCES SYMPOSIUM

PEG TSAO
OVERVIEW OF THE CRU PROGRAM

KATHLEEN THOMPSON & RUTH O’HARA
WHEN & WHERE TO OBTAIN A CE PI WAIVER

We'll start shortly...
INAUGURAL Clinical Research Resources Symposium
Held last Thursday, August 17, 2023
INAUGURAL
Clinical Research Resources Symposium
300-Plus Participants
INAUGURAL Clinical Research Resources Symposium

26 Exhibitors
INAUGURAL Clinical Research Resources Symposium

Representatives from:
CRUs, Oncore, SoM Service Centers, Research Participant Engagement Services, Trial Innovation Network (TIN), Community Engagement, Workforce Development, TDS, CTRU, iBERD and many more
INAUGURAL
Clinical Research Resources Symposium

Objective:
Informational and networking event. Individuals from the School of Medicine Research Office were available to provide information on services and answer questions.
INAUGURAL
Clinical Research Resources Symposium

Launch of Inaugural 2022 Fact Book

20 Pages of facts and figures focused on patient-driven research, the offices and services that enable that research, and metrics on our achievements.

Download at: med.stanford.edu/researchoffice.html
INAUGURAL Fact Book

MCHRI creates better lives for children and mothers by increasing high-risk, high-reward research, and speeding the most promising discoveries to patients. We invest in people, especially young investigators. The vast majority of scarce NIH funding goes to late-stage research and typically to older investigators. Our brilliant young scientists – some of our boldest thinkers – have the least access to resources to test their ideas. The bulk of MCHRI funding is increasingly targeted to early-career fellows, post-docs, and faculty to provide resources of time to think and funds to take risks.

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<th>Section</th>
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<tr>
<td>Studies in Intake Portal</td>
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<td>CRC Intake Requests</td>
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<td>Studies Supported</td>
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<td>D3 Trainees</td>
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INAUGURAL Fact Book

Clinical & Translational Research Unit (CTRU) 2022

PI Clients: 145
Departments Represented: 75
Clinical Research Studies: 391
Federally or Foundation-Supported Studies: 127
Industry-Sponsored Studies: 192
Pediatric Studies: 45
COVID-19 Studies: 11

Download at: med.stanford.edu/researchoffice.html
INAUGURAL Fact Book

How Stanford CTSA’s Interactive Network Capacity Advances Clinical & Translational Research & Education

Department of Health of Solano and Santa Clara Counties’ California state public/private research partnerships focused on development of applications of their Health Information Exchanges to assure evidence-based practice for all residents of the county.

Center for Health Research for Kaiser, Northwest Region Collaborative research venture growing the database on the striking heterogeneity of health across Asian and Pacific Islander subpopulations and in particular among multi-racial groups not heretofore studied.

University of Hawai’i (UoH) Collaborative venture to allow junior faculty to develop the skills necessary to assess a system of care that embraces cultural values and practices, and empowers community through collaborative research.

Download at: med.stanford.edu/researchoffice.html
Clinical Research Quality (CRQ)

Time to Results Submission 2022
CRQ provides robust support to Stanford investigators to submit clinicaltrials.gov results within one year of their study’s primary completion date (PCD).

For results due in 2022, Stanford’s time to results submission was a median 362 days (IQR: 287, 389) following PCD; NIH reported a median of 400 days in FY’2022 (IQR: 349, 477.5).

63% On-time Submission

Download at:
med.stanford.edu/researchoffice.html
Got Feedback?
We are looking ahead to next year...

We would appreciate your feedback on the Inaugural Factbook and Symposium. We understand that you are busy, but we welcome the opportunity to learn what worked and what didn’t and hear your thoughts on areas where we might expand or highlight further.

Thank you!

Email Feedback to:
officeofsadr@stanford.edu
Clinical Research Units (CRU)

Peg Tsao, RN, CCRC
Associate Director
Clinical Research Operations

Maya Berdichesky, DMD
Manager, Trial Innovation Network
CTSA Hub Liaison
Spectrum CTSA Specific Aim

**Aim 1:** Create a local organizational framework to ensure high-quality clinical and translational research and operational success related to participant and clinical interactions within the context of an outstanding care delivery system.

- **Aim 1A:** Develop a new organizational structure composed of Clinical Research Units (CRUs) across the School of Medicine and affiliated centers. The CRUs will consist of teams of investigators within departments, divisions, or institutes organized to optimize their ability to provide compliant, efficient, and cost-effective CTR.

- **Aim 1B:** Create best practices for the CRUs and an intuitive dashboard to provide and assess metrics of productivity, efficiency, and team and research subject satisfaction.

- **Aim 1C:** Strengthen centralized clinical research administrative functions and assessment tools.
Growth

Stanford has experienced prolific growth in both the School of Medicine (SoM) and its healthcare system in past 10 years:

- Faculty growth
  - From ~1,000 to over 2,400
  - Majority clinical educators/researchers

- Healthcare System expansion
  - New adult hospital
  - New children’s hospital
  - Tri-Valley community hospital
  - Stanford Medicine Partners
  - Packard Children’s Health Alliance

- Clinical research ecosystem has developed
More Growth

Clinical research expenditures dramatically increased from Fiscal Year 2017 to 2022:

- $657M to $861M (31%)
Departments/Division have control

- Provide a centralized protocol review process that is equitable and transparent
- Provides metrics for departments/divisions to understand their overall clinical research portfolio
- A systematic structure to engage faculty and staff in communal effort to enhance review and oversight of clinical research.

Goals:

- Create organizational framework at department/division level
- Promote high quality research and operational success
- Enhance collaborative opportunities
Why change is needed – OB/GYN

A lot of great research done... in silos

OB/GYN in 2017

- 59 of faculty
- #54 on NIH ranking in OB/GYN
- Chair the primary contact for scientific reviews
- Issues with department research finances
- Protocols opened without anyone knowing

Image by Anahi Alanis

Slide courtesy of Anna Girsen
Why change is needed - Hepatology

- Multiple Hepatologists conducting clinical research independently
- Some clinical trials with low or no enrollment
- Defined goals to standardize evaluation of protocols
- Sponsored research and investigator-initiated research protocols can be assessed for feasibility, resources, and enrollment targets

*Slide courtesy of Paul Kwo*
CRUs Facilitate Change

- Increase efficiency and flexibility by:
  - Creating a process for assessment of proposed studies
  - Provide guidance and access to support and resources
  - Leverage knowledge and experience
  - Respect researcher’s autonomy and creativity
  - Promote the use of metrics

- Increase scientific integrity:
  - Review and advice early in process
  - Identify and facilitate collaborative opportunities
CRU Review Ensures

✓ Scientific Validity review completed
✓ Budget feasibility
✓ Operational feasibility
✓ Cohort availability
✓ Available vs. needed FTE%
✓ Competing studies
Broader Impact

Multiple anticipated and unanticipated benefits

- Central resource within the department/division for staff and faculty research support
- Facilitate access for staff and faculty to Spectrum resources

- Silos being bridged across division/department framework thru CRU leadership committee
  - Team science opportunities are being recognized and pursued
  - Diversity, Equity and Inclusion initiatives being integrated across CRUs
CRU: Entry Portal to Resource Ecosystem
Communication/Information Dissemination

1. Quarterly Leads meeting with faculty and department level staff leads
   • Dissemination of key operational information
2. Quarterly meetings with all staff leads
   • Identify pain points and create process improvements
   • Creating a community of practice
3. Dedicated web presence on Spectrum [website]
4. Presentations at department meetings
Current State

- Every clinical department has at least 1 CRU
- 12 of the 18 clinical departments have CRUs fully launched in all divisions
- CRU framework and community has been widely accepted and promoted
CRUs Foster Clinical Research Success

- Facilitates a thorough examination of the quality of research, coordinator time, and budgeting of new studies
- Constructive feedback from an impartial source makes a submission stronger
- Smooth and centralized process/paperwork
- Refined tools
- Easier to track timelines
- Standardized study feasibility kick-off meetings
Working Together

OnCore
- Study management
- Committee management
- Tracking/reporting/accred progress

Clinical Research Units (CRUs)
- Protocol review
- Compliance checks
- Enrollment goals

Research Participant Engagement Program
- Recruitment planning
- Engagement resources
- Outreach via Epic/email

Trial Innovation Network
- Consultations & resources for multi-site clinical research (e.g., proposal development, study operations, national recruitment & retention)

https://med.stanford.edu/spectrum.html
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Trial Innovation Network
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Questions & Discussion
Announcements

• Scientific and Scholarly Validity Review [FAQ]
• Translation Services information
• Clinical lab
  • Clinical Lab Reference Range Memo
  • Clinical Lab Reference Ranges - Spectrum Regulatory Memo

• Reminders to review research billing reports
  • Be sure to have participants contact the study team if they are unsure
WORKFORCE DEVELOPMENT
Education and Training

ESSENTIALS OF CLINICAL RESEARCH
10-week course on the fundamentals of clinical research: design, analysis, Good Clinical Practice (GCP), management, and regulatory requirements

KL2 MENTORED CAREER DEVELOPMENT PROGRAM
two-year partial salary support and advanced training in clinical and translational research

CLINICAL RESEARCH OPERATIONS PROGRAM
weekly classes on clinical research including operations and Good Clinical Practice

FACULTY

POST-DOCS

RESEARCH CAREER ACCELERATOR PROGRAM (ReCAP)
monthly seminars on professional development for career development award recipients

INTENSIVE COURSE IN CLINICAL RESEARCH (ICCR)
week-long course on fundamental principles of study design, biostatistics, informatics, regulatory issues, and bioethics in a highly intensive immersion setting

STAFF

MEDICAL BOARD OF CALIFORNIA

BRN California Board of Registered Nursing
# Calendar of Training Opportunities

## August 2023

<table>
<thead>
<tr>
<th>Date</th>
<th>Categories</th>
<th>Organizers</th>
<th>Tags</th>
<th>Venues</th>
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<tbody>
<tr>
<td>1</td>
<td>10:00am</td>
<td>Lane Library: Understanding NIH Data Management and Sharing Requirements</td>
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<tr>
<td>1</td>
<td>9:00am</td>
<td>The Informed Consent Process</td>
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<td>10:00am What's New with the CTRU</td>
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<td>6</td>
<td>10:00am</td>
<td>Lane Library: Keeping Current: Stay Up to Date with the Latest Biomedical Research</td>
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<td>13</td>
<td>12:00pm</td>
<td>Communication: Managing Difficult Conversations</td>
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<td>10:00am Inaugural Clinical Research Resources Symposium</td>
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<td>13</td>
<td>12:00pm</td>
<td>Lane Library: You Really Need a Protocol!</td>
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<td>9:00am: Clinical Research Budgeting Part 2: The Budget and Billing Workbook</td>
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<td>20</td>
<td>9:00am</td>
<td>Study Start-up</td>
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<td>20</td>
<td>12:00pm</td>
<td>Clinical Research Budgeting Part 1: RMO Processes and Estimating Costs</td>
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<td>10:00am: ACRM Networking Event (in-person)</td>
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<td>27</td>
<td>10:00am</td>
<td>Clinical Research Budgeting Part 2: The Budget and Billing Workbook</td>
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*Note: [Calendar URL](#) for more details.*
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- **September 2023**
- **Categories**: 
  - Intensive Course in Clinical Research - Sept 9 - 15, 2023
  - Diversity & Health Equity in Clinical Trials
  - Research Billing
  - ClinicalTrials.gov Registration
  - Increasing Diverse Representation in MGH Studies
  - ClinicalTrials.gov Overview
  - Research Career Accelerator Program (ReCAP) Seminar Series

- **Organizers**:
  - The Informed Consent Process
  - Working with the Office of Research Patient Care Services
  - Understanding Phases of Research and Study Designs
  - Biospecimen Sampling in Clinical Research
  - eProtocol Submissions for new studies
  - STARR and OMOP: An Overview

- **Tags**:
  - ClinicalTrials.gov

- **Venues**:
  - 9:00am
  - 12:00pm
  - 12:15pm