Town Hall Meeting

WITH DR. RUTH O'HARA
SENIOR ASSOCIATE DEAN FOR RESEARCH

JULY 29, 2022
10:00 - 11:00 AM

We'll start shortly....
Agenda:

- **Dr. Ruth O’Hara**, Senior Associate Dean for Research – School of Medicine; Professor, Department of Psychiatry: Welcome

- **Dr. David Strick**, Director of Safety & Emergency Management: Update on Covid Policies

- **Katherine Connors**, Associate Director, Research Participation Program: Research Participation Program

- **Rajnesh Prasad**, Assistant Dean; Executive Director of Spectrum CTSA: OnCore (Non-cancer) Updates

- **Shonna Simpson**, Technology and Digital Solutions: OnCore Financials Project Kick-Off
Are there recent changes to the rules?

- Covid-19 Policies and Procedures have remained the same.
- We have altered the Covid-19 cleaning paradigm.
- We are continuing to have our housekeeping staff clean high touchpoints in our buildings (railings, door knobs, conference rooms, kitchens, restrooms).

Are we required to wear a masks?

- Stanford already **strongly recommends** masking indoors and in crowded outdoor settings, and requires masking in classrooms, healthcare facilities and Marguerite buses. The new community level means that masks must now be worn indoors at SLAC due to DOE requirements. Other university requirements are not affected.

Do I have to receive the Covid-19 notices?

- Yes, we are required to distribute these broadly as part of California Assembly Bill 685.
Question: I’m Covid-19 positive, now what do I do?

• Enter your positive test into healthcheck.stanford.edu
  – Include the positive test date.
  – Include your contacts in the 48 hours before you became symptomatic or 48 hours before testing positive if you are asymptomatic.
  – Include what buildings you were present and the dates
  – Include date your symptoms started.

• Healthcheck will issue you a return-to-work date.

• Medical support team may call.

• Return to work for individuals with hospital duties is different from the University. HRT

• All of this information applies to (My husband/wife/partner is positive with Covid)

• We do ask that you inform people that you were in contact with that you tested positive for Covid-19.
Question: I did my antigen test at 7 days and it is negative, can I come back to campus now?

Faculty, staff, and postdocs may qualify for earlier return to campus on day 7 following a positive test/symptom onset, if they meet the following criteria:

- **Fully vaccinated**
- Fever-free for 48 hours and with improving symptoms
- An employee whose job requires an on-site presence
- Rapid-tested* negative on day 7

Faculty, staff, and postdocs who meet the criteria above AND who have a critical need to return to campus prior to the end of their 10-day isolation period, may contact the Medical Support Team at employeecovidclearance@stanford.edu with questions about obtaining rapid antigen tests.

Faculty and staff, and postdocs who meet the criteria above must email employeecovidclearance@stanford.edu to request early onsite access.
Contact Information

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650-709-5466

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sommenemergency@stanford.edu
medfacilities.stanford.edu
Research Participation Program
EngageParticipants@stanford.edu

Katherine Connors
July 29, 2022

Stanford’s Research Participation Program is supported by the Stanford CTSA Award Number UL1TR003142 from the National Center for Advancing Translational Science (NCATS), a component of the National Institutes of Health.

https://med.stanford.edu/spectrum/study-team-resources/participant-engagement.html
Research Participation Program

provide resources and tools… with a focus on engaging participants as partners in research

• Participant recruitment consultations with study teams

• Participant Engagement Platform (PEP) **honest broker study invitations**
  – Direct Email, Children’s Epic MyChart, Postal Mail, and soon… **SHC Epic MyHealth**

• Community engagement guidance and referrals to our Office of Community Engagement, Community Advisory Board (CAB) for Clinical Research, and Maternal & Child Health Community-Engaged Research

• Social media campaign resources

• Guidance about other resources at Stanford, such as our Research Registry, and externally, such as the CTSA Trial Innovation Network
# Outreach Methods – What is Honest Broker

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<th>Current Methods</th>
<th>Pros</th>
<th>Cons</th>
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<td>PI/Physician contact</td>
<td>Often promotes physician-patient relationship, trusted advisor, coordinator of care</td>
<td>Time intensive for physicians and study team</td>
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<td>Physician referrals</td>
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<td>Not scalable for large outreach efforts</td>
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<td>Clinic visit</td>
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<td>Not applicable for all studies</td>
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<td>Flyers</td>
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<td>Community Events</td>
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<th>Additional Method – “Honest Broker”</th>
<th>Pros</th>
<th>Cons</th>
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<td>An honest broker (trusted 3rd party) conducts outreach on behalf of the study team/physicians</td>
<td>PHI not shared with study team until patient expresses interest; Privacy and Compliance</td>
<td>Does not leverage treating relationship</td>
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<td>Service provided following SOP and recruitment best practices</td>
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<td></td>
<td>Access to data and tools support scalable, large outreach efforts</td>
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Stanford Research Repository (STARR) Tools

- https://med.stanford.edu/starr-tools.html
- Stanford Medicine's approved resource for working with clinical data for research purposes
- Pulls EHR data from both hospitals and ancillary clinics daily
- The home of two web tools:
  - **Cohort Discovery**
    Pre-IRB, de-identified data, patient counts based on criteria, including key words from clinical documents/notes
  - **Chart Review** (self-provisioned or custom with Research Informatics Center (RIC))
    Requires IRB/Privacy approval
- Can only outreach to own patients*. Enter honest broker!
Participant Engagement Platform (PEP)

- Our PEP workflow identifies potential participants by applying the study inclusion/exclusion criteria to Stanford’s STARR database.

- If study team wishes to use both Epic MyChart and Direct Email, PEP determines best method of contact based on participants’ Epic (MyChart account/usage) or Email contact availability.

- Research Participation team serves as the Honest Broker through the PEP

- PEP tracks age/race/sex/gender metrics. We can modify outreach to increase representation.
Working together

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

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

CRU
- Protocol development and review
- Compliance checks
- Enrollment goals
• Pulls Cohorts from Stanford’s Electronic Health Record database (STARR)
• Validates study is Open to Accrual in OnCore prior to outreach
• Screens outreach against on study participants in OnCore and from a global opt-out list to prevent inappropriate outreach
• Identifies best outreach channel (Direct Email, Epic MyChart/MyHealth, Postal)
• Generates system friendly participant listing to be used by outreach software (e.g. Qualtrics)
• Tracks the outreach progress for studies
Research Participation Program Expands

- In response to increased demand from study teams and to better serve the greater Stanford research community
- To increase opportunities to participate in research for people of all backgrounds

- Our model includes one-hour free consultations and an array of services for study teams, including Direct Email, Epic MyChart, Postal Mail, and Stanford Research Registry outreach.

- Visit our website for Standard and Add-On Services and their associated costs, as well as for Participant Engagement Tips and Resources and a “How to Plan a Recruitment Budget” template.
Introducing Participant Engagement “Office Hours”
2nd and 4th Fridays 1pm, Zoom link (see website)

Thank you. Questions?
EngageParticipants@stanford.edu
Katherine Connors, Research Participation Program

Stanford Medicine
Office of the Senior Associate Dean of Research
OnCore (Non-Cancer) Updates
OnCore Bulk Studies Registration

Stakeholder Impact:
- Reduces duplicate effort for registering a study using the OnCore Request Portal
- Study teams will continue to focus on tracking the status and accrual of their study in OnCore.

Status: Completed - 100% of all eligible studies are registered into OnCore
- Moving forward, IRB approved studies that meet the SoM policy are automatically uploaded and registered into OnCore.

Completed: July 2022 – Completed ahead of schedule.
Effort Tracking

**Stakeholder Impact:**
- Effort Tracking Categories have been updated and condensed from 60 to 12 categories.
- Allows protocol staff to record effort for a specific study or for non-study specific tasks.
- Provides aggregated data to educate others on what each specific study entails.
- Informs resource decisions when new studies come on board.
- Provides data to justify the length of time tasks take.

**Status:** Pilot Phase
- Super users are currently testing the updates. Pilot phase will be completed by August 5th.

**Anticipated Completion:** September 1, 2022
Single Sign-On (SSO) for OnCore Access

Stakeholder Impact:

- Eliminates the need to enter password when accessing OnCore, eliminates need to log in when timed out from OnCore, and eliminates “User Account Locked” messages.

Status:

- The SSO authentication has been tested and deployed.
- Conversion of existing active user accounts will begin in August.

Anticipated Completion: September 30, 2022
OnCore and REDCap Integration
SADR & TDS Joint Initiative

Stakeholder Impact:

- Eliminates the double entry effort of registering participants in both REDCap and OnCore.
- Resolves discrepancies between the registered participants in the two systems.
- Study teams can automatically sync up the list of participants.
- The integration is bi-directional between the two systems.
- Enforces security – only staff listed on the protocol can access the application.

Status:

- The Unit and QA testing was successfully completed by the REDCap and OnCore teams.
- Super users are currently testing the application. Based on their recommended enhancements, the final version of the integration will be rolled out.

Anticipated Completion: October 1, 2022
Upcoming

**Brown Bag Lunches:**
A series of Brown Bag lunches will be held this Fall that will describe how Clinical Research Units (CRUs) can utilize OnCore features to better manage the CRU review process and study tracking. These sessions will also provide opportunities for study teams to interact in person with CRU and On Core support staff and collaborate with other School of Medicine study teams.

**Tableau Dashboards:**
The OnCore team will be consolidating the current OnCore Tableau dashboards for department chairs and division managers, making them easier to navigate.
OnCore Resources

**Office Hours:**
We offer 30-minute office hour sessions each month for any OnCore questions (zoom or in-person). Watch your email for announcements!

**OnCore Basics Training (non-cancer studies):**
We offer Zoom and Online (self-pace) training. Information is available at [https://med.stanford.edu/spectrum/study-team-resources/oncore-for-non-cancer.html](https://med.stanford.edu/spectrum/study-team-resources/oncore-for-non-cancer.html)

For any other questions or inquiries, please contact us at: oncorerequest@lists.stanford.edu
Integrated Clinical Research Management

OnCore Financials and Billing Integration

7/29/2022
Agenda

1. Implementation Team Introduction
2. High-level Scope
3. Next Steps
Project Contacts

Shonna Simpson
Project Manager

Todd Ferris
Chief Technology Officer

Amanda Unrue
Business Analyst

Don Mitchell
Dir., Academic Application Services

Anthea Buchin
Manager, IT Research Systems

Sijo Thomas
Program Manager, Clinical Research Informatics
CRSO/SCH IT

Contact us at
oncore-financials@lists.stanford.edu
OnCore Financials and Billing Integration

Stanford Medicine is **enabling** real-time enterprise-wide research management

- Integrated, simplified and streamlined workflows
  - Decreased duplicate data entry reducing human error
  - Timely patient flagging to improve patient safety
  - Strengthen billing accuracy & minimize AR days

- Improved protocol execution by streamlining and standardizing existing processes and support mechanisms used by all study teams.

- Enterprise operational reporting and visibility
  - With all studies tracked in OnCore throughout the study lifecycle and integration with the EMRs and other systems, reporting and insights will be available to study teams, those supporting study teams, and the leadership of Stanford Medicine on the effectiveness of our clinical research.

- Integration between OnCore and Epic paves the way for Epic Research functionality

**Proposed Timeline:** FY Q4 2022 – Q4 2023
Next Steps

Project Kickoff
• All stakeholders
• Communicate project goals, scope, timeline, and the purpose of the project

OnCore Demo
• All stakeholders
• Demonstration of OnCore financials functionality

Workflow Workshops
• Coordination Team
• Define detailed workflows and processes from initiation to invoicing and payments - protocol initiation, subject mgmt., post-award
Any Questions

Contact us at
oncore-financials@lists.stanford.edu