Research Participation Services

April 8, 2021

Katherine Connors
EngageParticipants@stanford.edu

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Problem Statement

Majority of studies don’t draw enough participants!* 

- Participant recruitment is one of the greatest challenges to successful clinical research. Stanford has lacked tools and processes that can significantly increase participation while ensuring patient privacy and data security.

- Clinical Trials also suffer from a lack of diversity and inclusion. Stanford is seeking ways to adequately represent diverse populations in clinical trials.

Outreach Methods

**Current Method:**

**Physician Contact, Clinic Visit, Community Event, Flyers**

Physicians or study team inform patients about the study.

- Promotes physician-patient relationship, trusted advisor, coordinator of care
- Time intensive for physicians and study team
- Not scalable for large outreach efforts
- Not applicable for all studies

**Additional Method:**

**Honest Broker Contact**

An honest broker (trusted 3rd party) can conduct outreach on behalf of the study team/physicians.

- Trusted advisor outreach
- PHI not shared with study team until patient expresses interest, Privacy and Compliance
- Service provided following SOP and recruitment best practices; can be audited
- Knowledge and access to data and tools to support scalable, large outreach efforts
Research Participation Services

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

- Participant recruitment consultations
- Participant Engagement Platform (PEP) honest broker services
  - Direct Email, Children’s Epic MyChart
- Community engagement, including referrals to Stanford’s Community Advisory Board (CAB) for Clinical Research
- Social media campaign resources
- Guidance about other resources at Stanford and externally, such as the Trial Innovation Network

https://med.stanford.edu/spectrum/b1_8_rec.html
Research Participation Team

Katherine Connors, Program Manager
Maya Berdichesky, Trial Innovation Network Hub Manager

John Maul, PEP Project Manager
Todd Ferris, CTO, Advisor

Faculty Lead:
Karl Sylvester

Faculty Advisors:
Lisa Goldman Rosas
Ken Mahaffey
Research Participation Intake

• Contact EngageParticipants@stanford.edu

• Review:
  – Study synopsis, IRB # if available
  – Inclusion/exclusion criteria
  – Timeline; Enrollment goal and status
  – If applicable, recruitment strategies tried and recruitment materials/language
  – Onboarding capacity = # potential participants study team can screen/schedule in 24-48 hours
  – Other relevant information, such as compensation

• Discuss recruitment strategies and available services.
  – Confirm OnCore registration – Per Participant Accrual
  – Provide IRB modification guidance

• Note about COVID-19 impact on clinical research recruitment strategies: CRU Leads assisted study teams in acquiring approvals to modify/resume research activities post-COVID.
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
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 MyChart and Direct Email, the PEP platform 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 will soon track age/race/gender metrics. We can modify outreach to increase representation.
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, Phone)

Generates system friendly participant listing to be used by various outreach software

Tracks the outreach progress for studies
Participant Engagement Platform (PEP)

5 Channels:

1. **Direct Email using Qualtrics** for studies including healthy controls – Feb 2020
2. **Epic MyChart (Children’s)** secure portal – Mar 2020
   - Pilot BPAs for COVID-19 survey for peds cancer – Jun 2020
3. **Epic MyHealth (SHC)** secure portal – 2021
4. **Research Registry** with COVID-19 focus – Apr 2020
   - Sign-up via study directory (COVID-19 pilot Dec 2020) – 2021
5. **Other Honest Broker services**: postal mail, phone calls, text messages – 2021
   - Pilot postal mail for Research Registry COVID-19 – May 2020

*Registry is an “opt-in” model. All other channels are “opt-out”*
<table>
<thead>
<tr>
<th>Potential Participants</th>
<th>Including Healthy Patients</th>
<th>Condition Based Only</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adult</td>
<td>Direct Email</td>
<td>Not Eligible for Direct Email</td>
</tr>
<tr>
<td></td>
<td>Epic MyHealth Invitation</td>
<td>Epic MyHealth Invitation</td>
</tr>
<tr>
<td></td>
<td>Postal Mail</td>
<td>Postal Mail</td>
</tr>
<tr>
<td></td>
<td>(Future Feature)</td>
<td>(Future Feature)</td>
</tr>
<tr>
<td>Maternal/Child</td>
<td>Direct Email</td>
<td>Not Eligible for Direct Email</td>
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<tr>
<td></td>
<td>Epic MyChart Invitation</td>
<td>Epic MyChart Invitation</td>
</tr>
<tr>
<td></td>
<td>Postal Mail</td>
<td>Postal Mail</td>
</tr>
<tr>
<td></td>
<td>(Future Feature)</td>
<td>(Future Feature)</td>
</tr>
</tbody>
</table>
Dear Patient,

We are writing to invite you to participate in a new research study. We are looking for participants 18 years and older who have been diagnosed with glaucoma (or possible glaucoma), as well as patients who have no glaucoma or other significant eye diseases for comparison.

**Name of Project:**
Glaucoma Pathways

**What we are trying to do:**
The study is focused on finding new ways to detect and monitor glaucoma and its treatments.

**Who is in charge of the project:**
Dr. Jeffrey Goldberg will be in charge of this project. Dr. Goldberg is a Professor and Chair in the Department of Ophthalmology at Stanford Medicine. He is very excited to continue to partner with families and individuals like you.

Would you like to learn more?

![Yes. I am Interested.](image)

![No. I am not interested.](image)

**What we would need from you:**
- One 1-2 hour visit at Byers Eye Institute and the Spencer Center for Vision Research (Palo Alto, CA), which may include:
  - vision exams
  - non-invasive pictures of your eyes
  - non-invasive brainwave recording
  - If you have done any of the above as part of your recent clinical care, you do not have to repeat them.

**No treatment or medications will be given as part of this study.**

**What you get for your time:**
If you are eligible, upon completion of your visit, we will reimburse you $20 per hour.

Where you can learn more:
If you would like to learn about other research studies, please visit the Stanford Clinical Trials Website. We look forward to talking to you soon.

Sincerely,
The Stanford Research Participation Program, on behalf of Dr. Jeffrey Goldberg

If you would prefer not to receive email correspondence from Stanford’s Research Participation Program, you can unsubscribe or contact us at respartresearch@stanford.edu or by phone 650-497-3612. For Participant’s rights questions, contact 1-855-680-2900. Reference IRB: 38851. Invitation email generated on December 9, 2020 12:47:48 PST.
“Email tickler” Notification of MyChart message:

Sender: DONOTREPLY@STANFORDCHILDRENS.ORG
Email subject: New Research Opportunity

Hello <first name last name>,

[“You have”] a new message regarding a research opportunity. Please respond by logging into your MyChart account. If you do not want to receive emails like this in the future, you can update your participation preferences after logging in.

Healthy regards,

Stanford Children’s MyChart Online Care Team

<LOG IN NOW>

**This is an automated message. Please do not reply to this message.**

Welcome (Girl-Sally)

- Schedule your Flu Shot.
- Enter your e-mail address to start receiving notifications about new information in your MyChart account.
- Join research studies for which you are a good candidate. You have a new study to review.

To Do

- Overdue health reminders
Learning and Memory Study

Can learning and memory contribute to the persistence of the pain process?... details

Dear [Parent/Guardian of <Child’s Name> ],

We are excited to tell you about a new research study. We are looking to partner with families who have children that are between 10 and 24 years.
Response options (Direct Email or Epic MyChart)

1. “Yes, I’m interested” → participant contact preference passed on to study team for follow-up within 24-48 hours
2. “No, thank you” → recipient will no longer be contacted about this study
3. “Unsubscribe” → recipient will no longer be contacted via Research Participation for any study
4. No response → may be re-invited a max of 2 times, 2+ weeks apart (Direct Email only)
Stanford Research Registry

The goal of the Research Registry is to support Stanford research participant recruitment, particularly for COVID-19 studies at this time.

Population: focused on Bay Area beyond Stanford, and open to everyone.

https://redcap.link/StanfordRegistry

Launched April 2020

As of Mar 2021: ~3,800 registrants,
~1,800 tested for COVID-19, ~500 positive,
~50 COVID hospitalized

Coming soon: Spanish translation

As of Nov 2020, the “COVID Long Haul Study” documenting persistent symptoms of COVID-19 infections recruited >90 participants using the Registry.
Community Outreach & Engagement

• We connect study teams with Office of Community Engagement (OCE) for recommendations on building community partnerships
  – Is this for simply advertising a study or working more in partnership?
  – “Best to build a partnership when you’re not asking for something”
  – OCE contact: communityengagement@stanford.edu

• Our Stanford Research Registry with COVID-19 focus is shared in the Community Town Halls, including Latino Town Hall, led by Office of Community Engagement

• The Stanford Community Advisory Board (CAB) aims to:
  – enable community members to participate in research planning and dissemination of findings.
  – provide feedback to researchers on recruitment strategies, including reaching specific populations.
  – CAB contact: nventre@stanford.edu
<table>
<thead>
<tr>
<th>Barriers to participation among racial/ethnic minorities</th>
<th>Potential solutions to overcome barrier</th>
</tr>
</thead>
<tbody>
<tr>
<td>Logistical</td>
<td></td>
</tr>
</tbody>
</table>
| Lack of awareness of clinical trials                   | - Recruit in community locations in partnership with local agencies  
|                                                       | - Patient navigators can increase awareness of clinical trials  
|                                                       | - Providers and staff can ensure that racial/ethnic minority patients are aware of clinical trial participation options  |
| Costs associated with participation in trials          | - Plan for adequate compensation to overcome logistical barriers  
|                                                       | - Communicate research related costs early and clearly  |
| Psychosocial                                           |                                       |
| Lack of trust in the Stanford healthcare system, and medical research in general | - Publicly acknowledge and apologize for past wrong doings  
|                                                       | - Patient navigators can increase trust  
|                                                       | - Diverse healthcare delivery staff  
|                                                       | - Extremely clear consenting process is important  
|                                                       | - Cultural competency training related to racial/ethnic minority participation in clinical trials  |
## Engaging Underrepresented Minorities (URMs)

<table>
<thead>
<tr>
<th>Barriers to participation among racial/ethnic minorities</th>
<th>Potential solutions to overcome barrier</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Psychosocial (cont’d)</strong></td>
<td></td>
</tr>
<tr>
<td>Fear of risks/adverse effects associated with being in a trial</td>
<td>Extremely clear communication and consenting process is important</td>
</tr>
<tr>
<td><strong>Structural</strong></td>
<td></td>
</tr>
<tr>
<td>Language barriers (study materials, study staff, etc)</td>
<td>Ensure accessibility related to language for all study materials and activities</td>
</tr>
<tr>
<td>Exclusion criteria that disproportionately limit eligibility among racial/ethnic minority patients</td>
<td>Examine exclusion criteria with a disparities lens to identify criterion that may limit racial/ethnic minority participation</td>
</tr>
</tbody>
</table>

*Adapted from Stanford’s Office of Community Engagement*

**Contact:** communityengagement@stanford.edu
Monoclonal antibodies for low-risk or asymptomatic patients diagnosed with COVID-19 less than 3 days ago...

This study is focused on low-risk patients who have symptomatic COVID-19 or patients who are asymptomatic. This study is evaluating an Investigational medicine in patients diagnosed with COVID-19. The study medicine are monoclonal antibodies that target the virus that causes COVID-19. These monoclonal antibodies can help prevent or reduce the spread of the virus within the body. The study is open to patients aged 18 and older from anywhere in the United States.

Study of a new medication for patients who tested positive for coronavirus (COVID-19) in the last 72 hours...

The goal of this study is to see if a study medication, called camostat, works and is safe for the treatment of COVID-19. We will determine if the medication improves your symptoms, reduces the time until you test negative for COVID-19, and look at any side possible effects. The study medication, camostat, is an anticoagulant medication that inhibits the action of platelets, which are cells that help the blood to clot.

Join a COVID-19 Vaccine Research Study

Let’s unite in the fight against COVID-19. Volunteers from diverse groups are needed to test the vaccine. The vaccine is being developed at the University of Stanford. The research team is looking for volunteers to help test the vaccine. Participants will be compensated for their time and effort.
Participant experiences after clicking “I’m interested”

Thank you for your interest. Please contact: studyteam@stanford.edu or call 650-555-5555

StudyPage

Study 1
- study title
- description
- who can participate
- etc

I’m interested

Call-to-action
Team is not on StudyPages

No online sign-up available. Visitor will be instructed to contact the team directly.

No pre-screen survey

Simple online signup. Name/email/phone number

Pre-screen survey

Study specific pre-screen survey. People who pass will get the opportunity to enter contact details (Name/email/phone)

Lung function in people with viral infections

Enter your info and the study team will contact you soon!

Your data is securely stored and only shared with the research team

Name
Email
Phone

Notify me of future research (opt-out anytime)

Submit

View the full Privacy Policy and Terms
100% At-Home Clinical Study to Help Patients with Atrial Fibrillation Stay Protected on their Blood Thinner Medications

Stanford University

"We're looking for people that are currently taking a blood thinner for Atrial Fibrillation - receive a free wireless BP cuff & EKG machine!"

Take survey to see if you qualify

Age: 55 years and older
Gender: Any
Keywords: Atrial Fibrillation, AFib, AF, "Telehealth, At home study, remote study, home devices, heart rhythm study, Blood thinner, Anticoagulation"
Type: At home clinical study
Target: 100 Participants

Description
Are you taking a blood thinner medication for AFib (atrial fibrillation) or AFlutter (atrial flutter)?

Stanford University researchers are conducting a 100% at home clinical study to help patients with atrial fibrillation stay protected on their blood thinner medications.

The goal of the study is to help you keep track of your blood thinner medication and help you learn more about your condition. Participate in this exciting new study without ever having to leave your home!

Using a study app plus a wireless home EKG sensor and blood pressure cuff, and regular app-based communications, we will help you understand your condition better and stay protected from blood thinner medication complications!

Schedule
Study duration and period
This study takes approximately 6 months

Contact
Jasmine LeCoursiere
jalecco@stanford.edu
855/800-8623

*1. Do you have a condition called atrial flutter, atrial fibrillation, or commonly ‘Afib’?

[ ] Yes
[ ] No

*2. Are you currently taking any one of the following oral anticoagulants?
Warfarin (Coumadin), Rivaroxaban (Xarelto), Apixaban (Eliquis), Edoxaban (Savaysa), Dabigatran (Pradaxa), or other

[ ] Yes
[ ] No

*3. Are you 55 years of age or older?

[ ] Yes
[ ] No

*4. Do you have a smartphone (iPhone 6S, iPhone 7 or above, or Android version 6.0 or above)?

[ ] Yes
[ ] No

*5. Have you ever received care (primary care or specialty care) at Stanford Health Care?

[ ] Yes
[ ] No

Next
Stanford StudyPages partnership: Social Media Campaigns workflow

Facebook Ad

Study Page

Pre-screen

After Signup

Signup confirmation screen with link to complete follow-up survey [REDCap link] +

Automated SMS text message (only people with a mobile phone)

1. Do you have a condition called atrial flutter, atrial fibrillation, or commonly ‘Afibs’?
   - Yes
   - No

2. Are you currently taking any of the following oral anticoagulants?
   - Warfarin/Coumadin
   - Rivaroxaban (Xarelto)
   - Apixaban (Eliquis)
   - Edoxaban (Savaysa)
   - Dabigatran (Pradaxa)
   - Other
   - Yes
   - No

3. Are you 55 years of age or older?
   - Yes
   - No

4. Do you have a smartphone (iPhone 6S, iPhone 7 or above, or Android version 6.0 or above)?
   - Yes
   - No

5. Have you ever received care (primary care or specialty care) at Stanford Health Care?
   - Yes
   - No

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Study: 100% At-Home Clinical Study to Help Patients with Atrial Fibrillation Stay Protected on their Blood Thinner Medications

Stanford University

“Are you taking a blood thinner medication for Afib (atrial fibrillation) or Atrial Fibrillation? Stanford University researchers are conducting a 100% at-home clinical study to help patients with atrial fibrillation stay protected on their blood thinner medications.

The goal of the study is to help you keep track of your blood thinner medication and help you learn more about your condition. Participate in this exciting new study without even having to leave your home!

Using a study app plus a wireless home EKG sensor and blood pressure cuff, and regular app-based communications, we will help you understand your condition.

Schedule

Study duration and period

This study takes approximately 1 month.

Contact

Jasmine LuCurziene

jlucurzi@stanford.edu

650-314-8003
Research Registry Management pilot

• Does your team have a Research Registry?

• Ripple Science is research registry management software, facilitating study-participant matching

• Ripple Science helps manage the back-end of multiple registries (school/dept/group levels), promoting participant preferences and ensuring opt-outs.

• Long-term goal: Merge our Research Registry (REDCap) with “registry” created by StudyPages directory engagement, along with other registries across SoM.
## PEP Metrics - Feb 2020 to Mar 2021

<table>
<thead>
<tr>
<th></th>
<th># in Wave</th>
<th># Bounced</th>
<th>%</th>
<th># Responded</th>
<th>%</th>
<th># Interested</th>
<th>%</th>
<th># Not Interested</th>
<th>%</th>
<th># Unsubscribe d</th>
<th>%</th>
<th><strong>PEP On Study</strong></th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>All</td>
<td>15864</td>
<td>229</td>
<td>1.44%</td>
<td>1128</td>
<td>7.11%</td>
<td>701</td>
<td>4.42%</td>
<td>398</td>
<td>2.51%</td>
<td>7</td>
<td>0.04%</td>
<td>268</td>
<td>1.69%</td>
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<tr>
<td>Direct Email</td>
<td>3483</td>
<td>222</td>
<td>6.37%</td>
<td>262</td>
<td>7.52%</td>
<td>156</td>
<td>4.48%</td>
<td>79</td>
<td>2.27%</td>
<td>6</td>
<td>0.17%</td>
<td>30</td>
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</tr>
<tr>
<td>Epic MyChart</td>
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<td>7</td>
<td>0.12%</td>
<td>260</td>
<td>4.36%</td>
<td>153</td>
<td>2.57%</td>
<td>107</td>
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<tr>
<td>Epic BPA</td>
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<td>0.21%</td>
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<td>20.35%</td>
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<tr>
<td>Typical Marketing</td>
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<td>23</td>
<td>20.35%</td>
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<td>20.35%</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>23</td>
<td>20.35%</td>
</tr>
</tbody>
</table>

**On Study data is collected at a point in time and may not reflect all people enrolled**
Thank you. Questions/Suggestions?

Katherine Connors, Research Participation Team Lead
EngageParticipants@stanford.edu