Research Participation Services

July 2021

Katherine Connors, Program Manager
EngageParticipants@stanford.edu

Stanford’s Research Participation Services are 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.
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.

- 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

Check out resources including “Recruitment Strategizing Worksheet” here: 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

- As of July 2021, PEP tracks 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)

6 Channels:

1. **Direct Email using Qualtrics** for studies including healthy controls – Feb 2020
2. **Epic MyChart (Children's)** secure portal – Mar 2020
   - Best Practice Alerts (BPAs) – Jun 2020
3. **Epic MyHealth (SHC)** secure portal – late 2021
4. **Other Honest Broker services:**
   - Postal Mail – May 2020
   - Phone Calls (“Deputized” Honest Broker) – May 2021
   - Text Messages – 2022
5. **Research Registry** with COVID-19 focus – Apr 2020
   - Sign-up via study directory (COVID-19 directory Dec 2020) – 2022
6. **Social Media Campaigns** – 2020

*Registry is an “opt-in” model*
<table>
<thead>
<tr>
<th>Participation Engagement Platform – available honest broker services</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Adult potential participants</strong></td>
</tr>
<tr>
<td>Including Healthy Patients</td>
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<tr>
<td>Direct Email</td>
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<tr>
<td>Epic MyHealth Invitation (Future Feature)</td>
</tr>
<tr>
<td>Postal Mail (Future Feature)</td>
</tr>
<tr>
<td><strong>Maternal/Child potential participants</strong></td>
</tr>
<tr>
<td>Direct Email</td>
</tr>
<tr>
<td>Epic MyChart Invitation</td>
</tr>
<tr>
<td>Postal Mail (Future Feature)</td>
</tr>
</tbody>
</table>
A note from the team: You are receiving this message because you or your family is cared for at Stanford HealthCare or Stanford Children’s Hospital. This message comes from the Stanford’s Research Participation Program. Stanford University’s Institutional Review Board (IRB) approved this way of finding people to join the study. The IRB is a group that protect the rights and welfare of people in research studies. This message meets state and federal rules for research studies. Your contact information has not been shared with any doctor or members of the research team.

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.

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.

Would you like to learn more?

Yes.
I am Interested.

No.
I am not Interested.

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

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 June 2021: ~7,500 registrants, ~3,700 tested for COVID-19, ~620 positive, ~65 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
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>Logistical</strong></td>
<td></td>
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</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>- Extremely clear communication and consenting process is important</td>
</tr>
<tr>
<td>Fear of risks/adverse effects associated with being in a trial</td>
<td></td>
</tr>
<tr>
<td><strong>Structural</strong></td>
<td>- Ensure accessibility related to language for all study materials and activities</td>
</tr>
<tr>
<td>Language barriers (study materials, study staff, etc.)</td>
<td>- Provide better access to, and expansion, of hospital interpreter services</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
Participant experiences after clicking “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.

**StudyPage**

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

I’m interested

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

**No pre-screen survey**
Simple online signup. Name/email/phone number

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

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 rhythms 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.

Schedule

Study duration and period
This study takes approximately 6 months

Contact

Jasmine LeCoustreine
jellaco@stanford.edu
(650) 800-0023

*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 (Elquis), 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
Stanford StudyPages partnership: Social Media Campaigns workflow

**Facebook Ad**

Stanford is conducting an at-home clinical study for people with Afib taking blood thinner medication.

**Study Page**

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*

**Pre-screen**

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/Imatinib
   - Rivaroxaban
   - 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

**After Signup**

Signup confirmation screen with link to complete follow-up survey

[REDCap link]

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

“Thank you for your interest in our research study! A link has been emailed to you to upload a photo of your prescription. Please check your email and call REDCap. Ask it any questions. If you are signing up Friday after 4 PM, we will be in touch with you Monday morning. Thank you!”
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 Jun 2021

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</tbody>
</table>

*Registry & Postal Mail responses assumed to be higher than normal due to COVID-19 / COVID-19 vaccine interest*
Thank you. Questions/Suggestions?

Katherine Connors, Research Participation Team
EngageParticipants@stanford.edu