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 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
Challenges & Tips - Getting Participants in the Door

- 11% of sites selected are never activated due to failure to enroll\(^1\)
- 80% of clinical trials fail to meet enrollment deadlines\(^2\)

- Try different channels early on and hone what is most effective

- Make sure to respond to participants within **24-48 hours** of hearing from them, regardless of their eligibility.

- Consider your online presence – study website, social media?

- Be thoughtful with language and images for reaching desired populations (age, race, caregivers vs. patients, etc.)

- Track results of all recruitment methods! Make sure to document how participants learned of your study.

\(^1\)Clinical Leader; From the Editor (May 30 2017),
\(^2\)Patient Recruitment and Retention; Forte Research Systems
What are Recruitment/Retention Materials?

“What recruitment is a **vital first step in the consent process that must not be coercive or misleading.**” - US Dept of Health & Human Services

• Must be reviewed and approved by IRB before use
• Intended to inform and encourage participation
• Often the first point of contact an individual has with a study

*The IRB’s determinations are **study-specific**, however, the following general guidelines can help facilitate IRB review.*

How are they used?

**Today’s focus**

Pre-Enrollment: Intended to broadly identify population of potential participants

Post-Enrollment: Intended to collect study data, improve retention of participants, and inform ongoing activities
Pre-Enrollment Materials

- Flyers, bulletin boards, other public signage
- Radio and newspaper ads
- Social media posts
- Targeted mailings
- Materials in a physician office (brochures, electronic display)

Target Population

- What are my participant population’s demographics?
- Where do they go for information?
- How do they engage with advertising content?
- What motivates my participant population—contributing to science, helping the community, personal therapy advancement?
A 2013 study from the Center for Information and Study on Clinical Research Participation (CISCRP) asked 5,701 respondents:

What do you think is the top reason people choose to participate in clinical trials? The report found:

- 33% of respondents said to advance medicine
- 29% said to help improve or save lives
- 15% said to help improve their condition

The top perceived benefits of participation have an altruistic and/or hopeful outlook, but these ideas can’t directly be used to encourage participation. An IRB won’t approve an ad it if it implies a specific end result or is considered promissory.
<table>
<thead>
<tr>
<th>Recruitment</th>
<th>Guidances</th>
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<tbody>
<tr>
<td>Advertisements: Appropriate Language - Recruitment Material</td>
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<td>Use of Employees or Laboratory Personnel as Research Subjects</td>
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<td>Non-English Speaking Research Participants</td>
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The IRB reviews recruitment materials to ensure they do not imply a certainty of favorable outcome or other benefits beyond those outlined in the consent document and the protocol.

The intent of these guidelines – to avoid coercion, and ensure that recruitment is fair, equitable, and not misleading - applies whatever the recruitment medium. See HRPP Ch 10 Equitable Selection.

Attach the following recruitment tools to the Attachments section in the eProtocol application (as applicable):

- **Social media ads** - e.g., on Facebook, Twitter, Instagram, Craigslist, or other sites
- **Flyers**
- **Email** recruitment scripts
- **Phone scripts and phone screens:** Attach in eProtocol under Waiver of Documentation (not in the Attachments section)

**Avoid the following content:**

a) **Payment:** Although advertisements can explain that subjects will be paid, they **should not** emphasize the payment or the amount to be paid, e.g.:

   i. **Do not** use larger font size, italics, underlining or bolding of the payment amount
   ii. **Do not** use statements such as “$10 for 10 minutes”, “$20 research study!”, “Participate in a fun research study for $10!”
   iii. **Do not** list payment or amount in the heading/title of the advertisement or in an email or Craigslist subject line.

b) **Avoid language** such as “fun research study,” since this is the researcher’s subjective opinion and would not necessarily describe the experience of the participant.

c) **Avoid any guarantee** that participation will benefit participants in any way (cure, improvement, etc.)
Consider including the following:

Generally, advertisements to recruit subjects should be limited to the information the prospective subjects need to determine their eligibility and interest.

When appropriate, the following items may be included in advertisements:

a) Name, phone number and address of the investigator and/or research facility;

b) Where an email address is included, it should be the institutional email address, e.g., “xxx@stanford.edu”, “xxx@stanfordmed.org” (not Gmail, etc.).

A Stanford email list (listserv) can be created for a specific lab or protocol so that several study personnel can receive the same email.

c) The condition under study and/or the purpose of the research;

d) In summary form, the criteria that will be used to determine eligibility for the study;

 e) A brief list of participation benefits, if any (e.g., a no-cost health examination);

f) The time or other commitment required of the subjects; and

g) The location of the research and the person or office to contact for further information

h) A statement, “Participant’s rights questions, contact 1-866-680-2906.”
Do You Have Depression?

If you struggle with Major Depressive Disorder, you may qualify for a clinical research study of an investigational medication. Eligible participants will receive all study-related care and study medication at no cost, and may be compensated for study-related time and travel. Health insurance is not required.

You may qualify if you are between the ages of 18 and 65 and suffer from depression.

Please call our Stanford study team at 650-555-5555 or visit www.depressionstudy.stanford.edu for more info.

Clinic located in Palo Alto. Study consists of three approximately 1 hour visits, and two 20 minute phone calls. For participant’s rights questions, contact 1-866-680-2906.
Recruitment Material Language Should Not:

• Be unduly influencing
• Be overly reassuring
• Promote *therapeutic misconception*
• Be coercive

“…unless otherwise informed, research subjects will assume…that decisions about their care are being made solely with their benefit in mind”

Constitutes “…a critical handicap to the subject’s ability to engage in an accurate assessment of benefits and risks”

- Appelbaum et al (1983)
Unduly Influencing Language

- Promising free treatment
- Emphasizing compensation
- Implying that a “cure” will be found
- Implying that the only or best hope for relief is to enroll in a clinical trial

“receive new treatments”  “new medication”
“new drug”  “free medical treatment”
Overly Reassuring Language

• “… is safe”
• “… is painless”
• “… involves a minor procedure”
• “… approved by a regulatory body”

As a participant in Rosacea Skin Study, you will have access to study doctors that ensure your safety, comfort, privacy, and convenience. Treatments are quick and painless.

Sign-up here for more information:
www.exampleskinstudy.stanford.edu
Overly Reassuring Language - Recommendation

- “… is safe”
- “… is painless”
- “… involves a minor procedure”
- “… approved by a regulatory body”

As a participant in Rosacea Skin Study, you will have access to study doctors that monitor your safety, comfort, privacy, and convenience.

Sign-up here for more information:
www.exampleskinstudy.stanford.edu
Promoting Therapeutic Misconception - Recommendation

- “Treatment”
- “Doctor”
- “Medical”
- “Experts”

If you have Symptoms of a Yeast Infection such as Vaginal itching, Burning, Irritation...

Stanford study Contact:
65-555-5555
yeaststudy@stanford.edu
www.yeastinfectionstudy.stanford.edu

Don’t
☐ Self treat yourself
☐ Buy medication at a pharmacy or grocery store

Do
☑ Find out if you qualify for a clinical research study. There is no cost to you.

A clinical research study is underway testing a medication for women experiencing yeast infections.

Participants must be:
~ 18 years or older, and not pregnant
~ Experiencing symptoms causing moderate to severe discomfort of a yeast infection- vaginal itching, burning, irritation.

Eligible participants will receive a gynecological exam, medication and follow-up visits. Compensation may be provided for time and travel.

Participant’s rights questions, contact 1-866-680-2906

[QR Code]
Coercive Language

- Intended to encourage enrollment and/or keep a participant enrolled
- Limits the “volunteer nature” of research studies

Excerpt from physician investigator letter:

“You may choose to withdraw your consent. This is of course not the ideal situation. Withdrawing consent means you will not continue to receive the benefits of the study, including free medical care and compensation for your time.”
Coercive Language - Recommendation

• Intended to encourage enrollment and/or keep a participant enrolled
• Limits the “volunteer nature” of research studies

Excerpt from physician investigator letter:

“You may choose to withdraw your consent. Withdrawing consent means you will no longer participate in study visits or have any information about you collected by the study team.”
Social Media as a Recruitment Tool

• Audience reach

• Same standards of IRB review apply to social media as all other recruitment materials

• Concerns:
  • Privacy breaches
  • Unblinding of study groups
  • Negative or misleading information
  • Skewed reporting of benefits
Creating a Protective Social Media Plan

• **Management and Monitoring**: How will you monitor user comments on a continuous basis and at what frequency?

• **Safety and Data Integrity**: How will you manage user comments related to safety, efficacy, or that are potentially influencing?
Creating a Protective Social Media Plan – Monitoring Examples

“Social media platforms require consistent review, as the privacy policies and administrative limitations are always evolving. Careful monitoring of all social media campaigns, including real-time monitoring of comments, shares, and tags, is constantly being done. While we can closely monitor campaigns and hide negative comments, we cannot completely disable commenting.”

“Comments across all channels will be reviewed twice per week day, and once per day during the weekend. These channels are constantly open on our digital marketer’s laptop, and a simple refresh is all that is needed to see the latest comments/tweets.”

Note: Quorum is an external IRB, one of a number of IRBs upon which Stanford investigators may rely when an appropriate reliance agreement is in place. Stanford has a Single IRB Manager, Sans Rayate, sans.rayate@stanford.edu, who can assist with reliance agreements and/or setting up single IRB review.
Creating a Protective Social Media Plan – Potentially Influencing Examples

“If the user tries to spread false statements on our social media channels, their comments will be hidden/deleted. (Hiding their comments makes it to where they will not be seen by anyone viewing our business page, but the user will still see the comment. Hiding comments is usually the best practice as the user still believes it is public, but in reality only we can see it. If we delete the comment, the user will be notified of its deletion and may be more apt to continue commenting to make their point.) They will not be banned unless the behavior continues in an aggressive manner.”

“When users ask acceptable questions, post acceptable comments, or message the page directly, it will be responded to very generally by providing the study website and study hotline.”

Note: Quorum is an external IRB, one of a number of IRBs upon which Stanford investigators may rely when an appropriate reliance agreement is in place. Stanford has a Single IRB Manager, Sans Rayate, sans.rayate@stanford.edu, who can assist with reliance agreements and/or setting up single IRB review.
Recruitment Materials Best Practices - Summary

• Balance between encouraging enrollment and protecting potential participants

• Accurate information at every stage improves participant engagement and protects trust

• Minor adjustments to language and images can make all the difference
Thank you. Questions/Suggestions?

Katherine Connors, Research Participation: EngageParticipants@stanford.edu
IRB Contact: irbeducation@lists.stanford.edu