New Research Recruitment Services

August 26, 2021

UT Health San Antonio
During the Forum:

*We ask you to please*

- Mute your mic to avoid background noise
- Keep your camera off to conserve bandwidth
- Join via Microsoft App to facilitate identifying UT Health San Antonio domain
- Use the chat feature and a moderator will respond to your question.
Overview

Initial Research Feasibility
Participant Recruitment Marketing Strategies
Budgeting for Recruitment
Velos eResearch, Pre-Screening
UT Health San Antonio IRB Guidance
Initial Study Feasibility

Jason Bates
Study Feasibility

When assessing the feasibility of a study, the following should be considered as applicable:

- **Study Design**
- **Patient Population & Enrollment**
- Competing vs. Complementary Projects
- Operations and Resources
- Financials
Study Design

• Do we have experience in the therapeutic area or indication being evaluated?

• Is the Study Design considered scientifically sound by the local investigator?

• Does the study have reasonable Inclusion & Exclusion Criteria given the study indication?

• Practical frequency of; visits, events or procedures.
Patient Population & Enrollment

- Direct access to the patient population being evaluated
- Given inclusion/exclusion do you think you can meet enrollment expectations
- Barriers to enrollment
  - Study Design
  - Alternative treatments
  - Cost to patients
  - Subject time commitment or expectations
Recruitment & Marketing Strategies for Clinical Trials

Linda Lopez-George, M.A.
Director of Research Marketing, Basic & Translational Science Marketing, Communications & Media
THREE WAYS TO INITIATE SERVICE

1. Clinical Trials Portal
2. Service Catalog
3. Email to Linda Lopez-George
Clinical Trials Portal

CTO Budget Analyst will initiate contact on behalf of the investigator when preparing a budget to negotiate with industry sponsor clinical trial

Recruitment & Marketing Team initiates the Service Request ticket and begins to prepare marketing plan designed to achieve the recruitment goals and provides the quote to the CTO within three (3) weeks.

Communication among the CTO and research team is managed through the service request ticket.
Service Catalog

Recruitment and Marketing for Clinical Trials

Service Description
Consult with faculty, staff and students on recruitment and retention marketing strategy for participants in human studies. Coordinate and liaise with other departments throughout the institution.

Services
- Consultation on participant recruitment for clinical trials will include a client discussion of
  - Recruitment strategy
  - Education on use of recruitment collateral
- Proactive strategy for increasing awareness of registries (ResearchMatch.org, Find A Study, Biobanks, Chromosome 18, etc.)
- Community outreach (health fairs, conferences, etc.)
- Liaison to the clinical and enterprise groups
- Plain language summary of the study

What to Expect

Details
Service ID: 40691
Responsibilities to Attain KPIs

Marketing Team Responsibilities

- Consult with requestor to determine if project aligns with strategic priority and goals.
- Provide scope of work based on project requirements.
- Communicate the status of the project to the requestor as needed.
- Coordinate with the requestor to align project goals with the final product.

Client Responsibilities

- Review checklist to assist in providing a summary of patient recruitment needs.
- Provide project description, trial protocol and supporting documentation.
- Respond to requests for additional information promptly.
- Provide measurable goals and metrics on key performance indicators.

Next Steps

1. Have your information and project ID (PID) ready before submitting the request.
2. You will be contacted in 1-2 business days to discuss your request.
Client Proposal
Client Proposal

**PROJECT OVERVIEW**

**BUDGET:** $300

**SOCIAL MEDIA**

Call to Action: driving to the Barshop Institute clinical trials webpage.

A/B test runs Weeks 1 and 2. The ad generating more engagement runs in Weeks 3 and 4.

Campaign metrics will be provided to the research team within 3 business days after the campaign ends. Metrics can support NIH grant budget justification, if required.

**SOCIAL MEDIA MANAGEMENT**

Facebook ad campaign will be managed by the Marketing, Communications & Media Digital team.

Facebook does not allow comments in sponsored ads to be disabled. Comments will be closely monitored and irrelevant or inappropriate comments can be hidden from view by the Digital team.

Paid ad campaigns can be suspended at any time to allow for evaluation of metrics and review of creative, as needed.
Sponsored Ad Prepared for IRB Review

Proposed ads for A/B Testing
UT Health San Antonio

If you are 65 or older, non-diabetic and a non-smoker, you may be able to help UT Health San Antonio researchers discover if using Rapamycin topical ointment can slow down the aging of skin cells. Eligible participants will be compensated.

To protect your privacy, please contact the study team directly using the link provided to discuss your eligibility or answer any questions.

Test A

Test B

UT Health San Antonio
Organic Tactics

- Institutional Digital newsletters
- News story pitched to the media
- UT Health San Antonio social media platforms (Twitter and Facebook)
- External digital newsletters (Bexar County Medical Society)
- Outreach Events (UTSA football home game)
Budgeting for Recruitment

Patricia Miranda
Clinical Trials Office
Manager, Research Operations
CTO Standard Budget Approach

Draft Coverage Analysis Step – Identification Point

- CTO Budget Team will identify whether a Sponsor's budget includes Advertising Budget
- When Research Teams anticipate the need for advertising funds, CTO Budget Analyst can request funds during negotiation
Ongoing study financial considerations

...once the study is ACTIVE

When patient enrollment is reached, patient retention is the next challenge!

Budget Amendments can be site initiated

Timing is key
Velos eResearch, Pre-Screening

Jason Bates
Tracking Recruitment Effort in eResearch

eResearch provides functionality to track recruitment efforts under each study:

After navigating to your study
1. Navigate to the Forms Tab
2. Select Recruitment Log and New
# Utilizing Recruitment Logs

1. To Start you will need to insert a start date
2. Patients can be entered by typing in the row, or
3. Users can use the search function to pull the patient in from Velos or EPIC

## Recruitment Log

**UT Health San Antonio**

Click on the *Patient Lookup* to populate the log with patient information. If the patient information is not found using the lookup, you may manually type in the patient information. When you are finished, you must scroll to the bottom of the log and click the **SUBMIT** button to save the log entries.

**NOTE:** Do not print PHI/PII data. To print/export a version of this log with PHI/PII removed, from the main toolbar menu, select **Reporting >> Custom Reports >> Recruitment Log**

**Initial Entry Date:** 08/02/2021

<table>
<thead>
<tr>
<th>Patient ID</th>
<th>Last Name</th>
<th>First Name</th>
<th>Middle Name</th>
<th>DOB</th>
</tr>
</thead>
<tbody>
<tr>
<td>123456</td>
<td>Patient</td>
<td>Recruitment</td>
<td></td>
<td>01/01/1965</td>
</tr>
<tr>
<td>60731483</td>
<td>PRELUDE</td>
<td>PATIENT</td>
<td>JANUARY</td>
<td>01/01/1980</td>
</tr>
<tr>
<td>80608581</td>
<td>CADENCE</td>
<td>PATIENT</td>
<td>UPGRADE</td>
<td>10/02/1965</td>
</tr>
</tbody>
</table>
Utilizing Recruitment Logs

1. Document the subject status and date
2. Include a reason
3. And comments as applicable
4. To save any update scroll to the bottom of the page and select submit.
Recruitment Log – Reports

Pull De-Identified list to share with sponsor or for invoicing supporting documentation.

1. Navigate to Reporting from the Velos eResearch top menu
2. Select Report Central
Recruitment Log – Reports

Within Reports Central

1. Select Custom Reports from the dropdown list
2. Select Recruitment Log
3. Select the study
4. Display
Recruitment Log – Reports

De-Identified report is rendered which allows several download options.

<table>
<thead>
<tr>
<th>Study Number</th>
<th>Initial Entry Date</th>
<th>Patient Study ID</th>
<th>Status Date</th>
<th>Status</th>
<th>Reason</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>CTMS 21-0013</td>
<td>08/02/2021</td>
<td>N/A</td>
<td>08/19/2021</td>
<td>Qualified for Screening</td>
<td>N/A</td>
<td>Subject scheduled for screening on 9/1/2021</td>
</tr>
<tr>
<td>CTMS 21-0013</td>
<td>08/02/2021</td>
<td>N/A</td>
<td></td>
<td>Excluded</td>
<td>Inclusion/Exclusion Criteria</td>
<td></td>
</tr>
</tbody>
</table>
Recruitment Log – End of Study

It is important to delete the report at the end of the study, as these are not subjects who consented for the trial.

1. Navigate to the Forms Tab
2. Select Recruitment Log and New
3. Select Delete and enter your e-Signature to save
IRB Requires Review of Recruitment Material

- The information contained in the advertisement
- The mode of its communication
- The final copy of printed advertisements
- The final audio/video taped advertisements
- Amount and schedule of any payments
Intent of IRB Review

Identify misleading or coercive language

No claims that the treatment is safe, effective, equivalent, or superior to any other treatment

Do not state or imply favorable outcome or benefits that may be different from protocol/consent form

For vulnerable populations, additional considerations are made
<table>
<thead>
<tr>
<th>The name and address of the investigator and/or research facility</th>
</tr>
</thead>
<tbody>
<tr>
<td>The purpose of the research</td>
</tr>
<tr>
<td>Basic eligibility criteria</td>
</tr>
<tr>
<td>A brief list of participation benefits, if any (e.g., a no-cost health examination)</td>
</tr>
<tr>
<td>The time or other commitment required of the subjects</td>
</tr>
<tr>
<td>The name and phone number of the person to contact for further information</td>
</tr>
<tr>
<td>May include statement that compensation for participation will be provided</td>
</tr>
</tbody>
</table>
Using Social Media to Recruit Participants

Identifying a list social media sites that are planned to be used

If public and private group interaction is planned, that a moderator has approved the interaction (or confirmation that there is no moderator)

Identifying how the research team will respond to group member messages

If additional sites will be used, providing the IRB with contents of the information
Recruitment using Social Media

- A plan to address privacy, confidentiality, data security, and identity verification for private messaging
- Include a description of any identifiable data that will be collected
- Include roles/responsibilities for posting, monitoring, and responding to recruitment communication - may be a service provided through third party contract
Advertisement that do **not** need IRB review

Source: https://www.pfizerclinicaltrials.com/find-a-trial/nct02464969
Advertisement that do **not** need IRB review

Source: [https://www.cfp.ca/content/cfp/suppl/2010/12/08/56.12.1375.DC2/Appendices_A-F.pdf](https://www.cfp.ca/content/cfp/suppl/2010/12/08/56.12.1375.DC2/Appendices_A-F.pdf)

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**Appendix A: Sample Study Invitation Letter to Recruit Practices for Waiting Room Surveys**

[Insert date]

Dear Sir/Madam,

The University of Ottawa has been funded by the Ontario Ministry of Health and Long Term Care to conduct a study that examines the way primary health care is organized in Ontario. Primary Health Care can be defined as the first point of contact for health care, such as the care you receive from your family doctor. The goal of this study is to understand what is working well in the primary health care system and to identify those areas that need improvement.

Patients provide very insightful information about our health care system. I am writing to request your participation in this study. With your help we can meet the study goals, creating a better health care system for you and your community.

If you agree to participate, we will ask you to complete a survey questionnaire (which will take approximately 15 minutes) regarding your experience in this medical clinic. Most of it can be filled out while you wait for your turn to visit the doctor. One page will need to be completed after the visit.

Participation is voluntary. You may withdraw from the study at any time and this would not affect your care in any way. The information you provide will be kept confidential. It will not include your name or any other identifying information, and no one at the practice will see your answers.

If you would like more information about the research, please speak with the Survey Administrator. We look forward to your involvement.

Sincerely,

[Signature]

**Investigator Name**
Principal Investigator
Study Name
Signature of Investigator
Advertisement that do **not** need IRB review
Advertisement that do **not** need IRB review

Young adults show serious complications from Type 2 diabetes

Published On: August 2, 2021
Shared by Will Sansom

UT Health San Antonio, University Health enrolled area children in TODAY studies.

Source: https://news.uthscsa.edu/young-adults-show-serious-complications-from-type-2-diabetes/
Institutional Form

<table>
<thead>
<tr>
<th>Item 7</th>
<th>Data / Specimen Storage Plan</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Not applicable, coded or identifiable information will not be collected</td>
</tr>
<tr>
<td></td>
<td>(None is checked in Column C - Identifier Table (Item 5) — skip to Item 8a)</td>
</tr>
<tr>
<td></td>
<td>Not applicable, see attached DAUR form</td>
</tr>
<tr>
<td></td>
<td>Check all that apply and complete the table as applicable</td>
</tr>
<tr>
<td></td>
<td>If data/specimens will be stored at more than one location list all applicable. If storage differs at the locations describe differences.</td>
</tr>
<tr>
<td></td>
<td>How will coded or identifiable data/specimens be stored?</td>
</tr>
<tr>
<td></td>
<td>Paper data (including completed consent forms)</td>
</tr>
<tr>
<td></td>
<td>Electronic data (consider the computing environment for all research data/images e.g., platform, number of computers, type of computers, network or standalone computers, access to data, security of physical environment, audit capabilities to track access activity, closed or open source informatics platforms)</td>
</tr>
<tr>
<td></td>
<td>REDCap</td>
</tr>
<tr>
<td></td>
<td>Refer to REDCap User agreement for requirements on data storage and access</td>
</tr>
<tr>
<td></td>
<td>Social Security Numbers (SSNs, Scrambled SSNs, or last four digits of an SSN)</td>
</tr>
<tr>
<td></td>
<td>Specimens</td>
</tr>
<tr>
<td></td>
<td>Long-term storage (following completion of the study and inactivation of IRB approval)</td>
</tr>
<tr>
<td></td>
<td>Social media recruitment and screening data</td>
</tr>
</tbody>
</table>

Note: If stored on VA server provide the path (e.g., /11vhatxmu15/VA Research/).
### Institutional Form & IRB Forms

<table>
<thead>
<tr>
<th>Column A</th>
<th>Column B</th>
<th>Column C</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Position Title (DO NOT MODIFY POSITION TITLES)</strong></td>
<td><strong>Column B</strong></td>
<td><strong>Column C</strong></td>
</tr>
<tr>
<td><strong>General research responsibilities</strong></td>
<td><strong>Oversight responsibilities</strong></td>
<td>For each position, list the minimum credentials and training required for any person assigned to this role. Use the following codes to identify the credentials &amp; training for the role you created in Column A.</td>
</tr>
<tr>
<td>1. recruitment</td>
<td>19-20. directing the research team members and assessing compliance with study protocol</td>
<td>A. Medical license (US)</td>
</tr>
<tr>
<td>2. assess inclusion and exclusion criteria</td>
<td>20-21. Lead PI - direct the study site PI(s) at other locations</td>
<td>B. Dental license (US)</td>
</tr>
<tr>
<td>3. obtain informed consent</td>
<td>21-22. determine significance of subject safety indicators (e.g., AE/SAEs, UADEs, SUARs, UPs, etc.)</td>
<td>C. RN license (US)</td>
</tr>
<tr>
<td>4. assist with the consent process</td>
<td>22-23. determine the significance of protocol deviations or violations</td>
<td>D. RPH license</td>
</tr>
<tr>
<td>5. source documentation or case report form completion</td>
<td>23-24. ensure the integrity of the data</td>
<td>E. <strong><a href="#">License</a></strong> license (US)</td>
</tr>
<tr>
<td>6. perform physical examination</td>
<td>24-25. Sponsor-Investigator monitoring and reporting <strong>...</strong></td>
<td>F. Good Clinical Practice (GCP) training</td>
</tr>
<tr>
<td>7. perform physical assessment</td>
<td>25-26. REDCap Study Administrator</td>
<td>G. Research related certification (e.g., CCRC)</td>
</tr>
<tr>
<td>8. obtain medical history or evaluate concomitant medications</td>
<td>26-27. Other:</td>
<td>H. Advanced academic degree</td>
</tr>
<tr>
<td>9. prescribe intervention being tested</td>
<td>27-28. Other:</td>
<td>I. <strong><a href="#">Certification</a></strong> certification</td>
</tr>
<tr>
<td>10. administer intervention being tested</td>
<td>28-29. Other:</td>
<td>J. <strong><a href="#">Certification</a></strong> certification</td>
</tr>
<tr>
<td>11. perform study procedures</td>
<td>29-30. Other:</td>
<td>K. Specialized training for the use of a device</td>
</tr>
<tr>
<td>12. adverse event inquiry and reporting</td>
<td><strong><a href="#">Redactors</a></strong></td>
<td>L. Other:</td>
</tr>
<tr>
<td>13. laboratory or <strong><a href="#">Other</a></strong> specimen handling</td>
<td><strong>...</strong> Requires IATA Training / Safety-Shipping Infectious Substances, Clinical Specimens, and Dry Ice <strong>...</strong> Requires GCP for <strong><a href="#">Investigator initiated</a></strong> studies of drugs, biologics or devices</td>
<td>M. Other:</td>
</tr>
<tr>
<td>14. specimen shipping</td>
<td><strong><a href="#">Recruitment</a></strong></td>
<td>Training requirements</td>
</tr>
<tr>
<td>15. investigational product dispensing &amp; accountability</td>
<td><strong><a href="#">Recruitment</a></strong></td>
<td>Scope of Practice requirements</td>
</tr>
<tr>
<td>16. regulatory &amp; essential documents, other record keeping or admin function</td>
<td><strong><a href="#">Recruitment</a></strong></td>
<td></td>
</tr>
<tr>
<td>17. review private identifiable information</td>
<td><strong><a href="#">Recruitment</a></strong></td>
<td></td>
</tr>
<tr>
<td>18. Direct REDCap access to identifiable study data (other than data entry)</td>
<td><strong><a href="#">Recruitment</a></strong></td>
<td></td>
</tr>
<tr>
<td>18-19. <strong><a href="#">Recruitment</a></strong>, monitoring, responding to social media recruitment communications</td>
<td><strong><a href="#">Recruitment</a></strong></td>
<td></td>
</tr>
</tbody>
</table>

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**Note:** Submit Inst-M Personnel Form (list of all research team members by name)

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At a minimum, all studies must have a Principal Investigator. Other suggested positions have been inserted below. Delete positions as appropriate to your study.
The Research Application consists of Early Notification for Clinical Trials through the Clinical Trials portal, Institutional Application and UTHSCSA IRB Application (when using UTHSCSA IRB).

Clinical Trials must be reviewed and cleared by the Clinical Trials Office (CTO) before UTHSCSA IRB Application documents may be submitted. CTO review is not applicable to human subjects research that does not meet the definition of a clinical trial.

Using this form—To check the checkboxes, double click on the box. To enter text in the text boxes, click once on the gray box and then type your response.

<table>
<thead>
<tr>
<th>Item 1</th>
<th>Is your study eligible for Expedited Review?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Applicable during initial IRB review of a new study</td>
</tr>
<tr>
<td></td>
<td>☐ Yes – confirm that a completed Form B-1 - Expedited Certification Form is included with submission and continue with the rest of this form</td>
</tr>
</tbody>
</table>
### Institutional Form & IRB Forms

**Item 10**  
First Contact - Recruitment  
*select how and where initial contact will be made with potential subjects; list all applicable*

<table>
<thead>
<tr>
<th>How will contact be made:</th>
<th>From study staff to participants</th>
<th>From participants to study staff</th>
<th>Briefly describe the plan to contact subjects including differences between groups (if any) --include details regarding relationship with subjects (i.e., members of treatment team will contact...)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Telephone call</td>
<td>[ ]</td>
<td>[ ]</td>
<td></td>
</tr>
<tr>
<td>Email</td>
<td>[ ]</td>
<td>[ ]</td>
<td></td>
</tr>
<tr>
<td>Mail</td>
<td>[ ]</td>
<td>[ ]</td>
<td></td>
</tr>
<tr>
<td>Waiting room (public)</td>
<td>[ ]</td>
<td>[ ]</td>
<td></td>
</tr>
<tr>
<td>During scheduled visit (private)</td>
<td>[ ]</td>
<td>[ ]</td>
<td></td>
</tr>
<tr>
<td>Other method:</td>
<td>[ ]</td>
<td>[ ]</td>
<td></td>
</tr>
</tbody>
</table>

**Will Social Media be used for recruitment?**  
[ ] No **continue to Item 11**  
[ ] Yes *(check all which apply and the remainder of this section)*  
[ ] Facebook  
[ ] Instagram  
[ ] Twitter  
[ ] Other: [ ]

**Indicate the type of recruitment activity using social media**  
[ ] Static *(a post or advertisement where there is no anticipated interaction)*  
[ ] Interactive *(a post or advertisement where interaction is anticipated)*  
[ ] Interactive with public group(s):  
  - [ ] Moderator approval is attached  
  - [ ] A Moderator does not exist  
[ ] Interactive with private group(s) – Include evidence of the group’s moderator approval  
[ ] Private messaging

**If interaction is planned, describe plans for responding to messages:** [ ]
Questions?
Concierge

- September 1, 2021
  *Wednesday from 9am - 12pm*

- September 7, 2021
  *Tuesday from 1pm - 4pm*

- September 15, 2021
  *Wednesday from 9am-12pm*

- September 29, 2021
  *Wednesday from 9am-12pm*

Register online for virtual concierge:
https://redcap.uthscsa.edu/REDCap/surveys/?s=FDYW D3JFJD