The fundamentals of recruiting representative populations in research and resources for achieving success

Shravani Chobhe, Bpharm, MSRA

Clinical Research Coordinator, II
University of Florida

Tara Pittman, MA, CCRP

Recruitment Manager
South Carolina Clinical & Translational
Research (SCTR) Institute
Medical University of South Carolina

Disclosures & Acknowledgements

UF | **Clinical and Translational Science Institute** | UNIVERSITY *of* FLORIDA

MUSC Medical University of South Carolina | South Carolina Clinical & Translational Research Institute

Slide 1

Learning Objectives

- Recognize the importance of recruiting representative samples for research studies and the need for early planning and budgeting a recruitment plan prior to protocol implementation to achieve this

- Explore methods for locating and effectively communicating with potential study participants, including those from historically underrepresented groups

- Gain insights from firsthand recruitment challenges and strategies, focusing on essential tips for new Clinical Research Coordinators to improve recruitment techniques

- Explore institutional and national resources to support recruitment efforts, enhancing participants' ability to navigate and improve recruitment processes in their own studies.

UF | Clinical and Translational Science Institute | UNIVERSITY of FLORIDA

MUSC Medical University of South Carolina | South Carolina Clinical & Translational Research Institute

Slide 2

POLL: Do you have personal experience recruiting participants for a research study?

- Yes
- No

UF | Clinical and Translational Science Institute | UNIVERSITY of FLORIDA

MUSC Medical University of South Carolina | South Carolina Clinical & Translational Research Institute

POLL: For those that have been involved in recruitment, has it ever been your primary responsibility on the study team?

- Yes
- No

UF Clinical and Translational Science Institute
UNIVERSITY *of* FLORIDA

MUSC Medical University of South Carolina
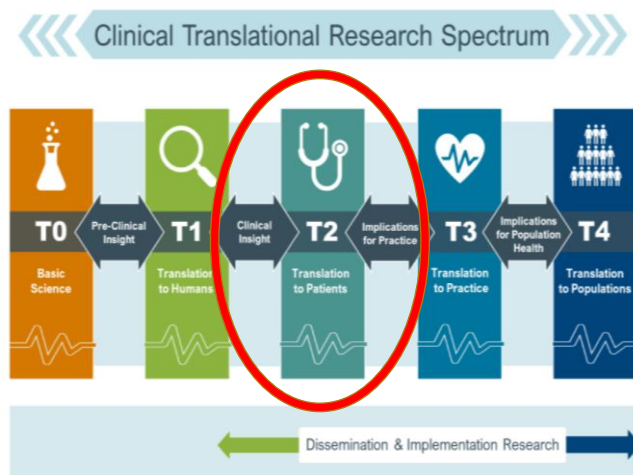South Carolina Clinical & Translational Research Institute

---

POLL: Consider the current or most recent study on which you've worked. Did you meet/are you meeting enrollment expectations?

- Yes
- No
- I don't know

UF Clinical and Translational Science Institute
UNIVERSITY *of* FLORIDA

MUSC Medical University of South Carolina
South Carolina Clinical & Translational Research Institute

Slide 1

POLL: Name one of the biggest recruitment challenges you've experienced. Please drop your answer in the chat.

We will be using these responses to create a graphic for the attendees following the event.

UF | Clinical and Translational Science Institute | UNIVERSITY *of* FLORIDA

MUSC Medical University of South Carolina | South Carolina Clinical & Translational Research Institute

Slide 2

Participant recruitment within the translational spectrum

Clinical Translational Research Spectrum

- Successful recruitment is necessary to demonstrate adequate efficacy for an intervention
- Poor recruitment often increases spending, decreases scientific integrity and slows speed at which a treatment is incorporated into care
- Over 80% of trials fail to enroll on time[1]
  - 37% will still under enroll, 11% not enrolling a single patient[2]
- Hitting the enrollment number is only one piece
  - The participant makeup should accurately reflect the diversity of the population for whom the intervention is designed

1. Desai M. Recruitment and retention of participants in clinical studies: Critical issues and challenges. Perspect Clin Res. 2020 Apr-Jun;11(2):51-53. doi: 10.4103/picr.PICR_6_20. Epub 2020 May 6. PMID: 32670827; PMCID: PMC7342339.
2. Chaudhari N, Ravi R, Gogtay NJ, Thatte UM. Recruitment and retention of the participants in clinical trials: Challenges and solutions. Perspect Clin Res. 2020 Apr-Jun;11(2):64-69. doi: 10.4103/picr.PICR_206_19. Epub 2020 May 6. PMID: 32670830; PMCID: PMC7342338.

MUSC Medical University of South Carolina | South Carolina Clinical & Translational Research Institute

Slide 1

Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies

Draft Guidance for Industry

Sponsors must submit Diversity Action Plans to explain rationale and goals for clinical study enrollment, broken down by demographics, and describe how the sponsor intends to meet those goals[1]

1. U.S. Food and Drug Administration. *Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies; Draft Guidance for Industry*. June 2024. https://www.regulations.gov/docket/FDA-2021-D-0789
2. U.S. Food and Drug Administration. (2024, June 26). *FDA Guidance Provides New Details on Diversity Action Plans Required for Certain Clinical Studies* [Press release]. https://www.fda.gov/news-events/press-announcements/fda-guidance-provides-new-details-diversity-action-plans-required-certain-clinical-studies

Participants in clinical trials should be representative of the patients who will use the medical products. The agency's draft guidance is an important step— and one of many ongoing efforts—to address the participation of underrepresented populations in clinical trials to help improve the data we have about patients who will use the medical products if approved.[2]

Robert M. Califf, M.D.
FDA Commissioner

MUSC
Medical University of South Carolina

South Carolina
Clinical & Translational
Research Institute

Slide 2

- Thoughtfully designed protocols are an important first step
  - Recruitment can only work when the protocol is not a barrier to participation
  - Striving to have any eligible individual who wants to participate, be able to participate
- NIH and others have continuously sited lack of awareness as being a major barrier to recruitment
  - about research in general and about the particular trial
- Not just about getting the study in front of people, but getting it in front of the RIGHT people, as efficiently as possible
  - Recruitment must be strategic and efficient.

AWARENESS IS KEY

MUSC
Medical University of South Carolina

South Carolina
Clinical & Translational
Research Institute

Set yourself up for success

- Successful recruitment almost always requires money
  - Not always for marketing/media
    - Consider participant incentives, community liaison support, community event expenditures, informatics fees
    - Requirements for representative populations (ex. Interpreter and translator services)
  - You can't be afraid to ask for what you need when writing applications
    - Should be a clearly articulated plan with accurate estimates
  - How much of your resources need to be allocated to finding participants outside of the enterprise patient population, in the community at large?
    - Conduct feasibility assessments when possible
- Understand what (if any) resources are provided by the sponsor, lead site, etc. and what are the recruitment responsibilities of each individual site
    - How do they align with existing institutional policies? (ex. social media)
- Create a recruitment calendar and refer to it regularly
  - What is the recruitment timeline?
  - How many participants need to be enrolled per week, month, etc.

MUSC
Medical University
of South Carolina
South Carolina
Clinical & Translational
Research Institute

Key factors in determining recruitment strategy

MUSC
Medical University
of South Carolina
South Carolina
Clinical & Translational
Research Institute

Characteristics beyond health status

- Helps to think of the population as product consumers
  - When selling a product, what kinds of things would you consider when advertising?
    - Where do they live? What kinds of media or messaging do they consume? What are their general likes and dislikes?
- Who do they turn to as trusted sources for key decisions?
  - Can't assume doctors are the most valued opinion for healthcare decisions
  - Is there a history of distrust in research that must be overcome?
- What are potential barriers to engagement?
  - Language, lack of reliable transportation, lack of childcare, accessibility concerns
- What incentivizes them to do things?
  - Don't assume potential benefits of an intervention is the incentive
- Remember that these answers may be largely different depending on demographic group

MUSC
Medical University of South Carolina

South Carolina
Clinical & Translational
Research Institute

From concept to practice

Message development across strategies

Simple and concise
- Flyer: Elevator ride or digital screen rotation
- Aim for 6th grade reading level
- Clearly state key eligibility requirements and next steps/contact info

Headlines and images should immediately reveal topic
- Study population should see themselves in the messaging
- Avoid being generic
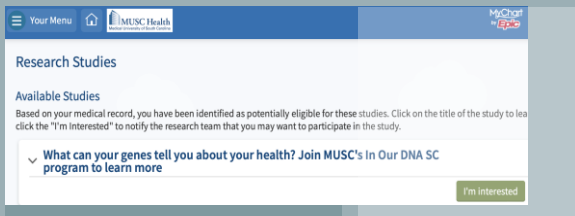
Appeal to needs and wants of population
- Available compensation, remote procedures, etc.
- More than one contact option (also helps with legitimacy in the digital space)

**Incorporate any required brand elements prior to IRB approval

---

Recruiting from the patient population

- Passive messaging vs. direct patient contact
  - Think beyond flyers. Be sure messaging allows for creative opportunities.
  - Electronic health records to identify eligible patients for contact
  - Warm vs. cold contact to approach patients
- Consider complexity of the patient population and other characteristics
  - Efficiency of EHR recruitment for complex inclusion/exclusion criteria
  - Numerous factors could influence approach to contacting identified patients:
  - Upcoming visits, use of patient portal, provider reinforcement, sensitivity and timing of diagnoses
  - Don't assume that an intervention or learning more about their condition is incentive enough

Social media considerations

- Is your participant population (or their decision makers) on social media? If so, which platforms? How do they engage?
  - Some platforms have more universal engagement (YouTube and Facebook), while others (Tik Tok and Snapchat) have a more specific user group
  - PewResearch.org
- What are your goals for engagement?
  - Recruitment? Survey distribution? Long term engagement/awareness?
- What are the team's available resources?
  - What is the budget? Can you afford paid ads? Can you outsource to 3rd party?
  - Does your institution's marketing/comms division offer support?
  - Do you have the team bandwidth to manage engagement
- Are there institutional policies or guidelines?

Pros and cons to social media use in recruitment

Pros

Pros	Cons
Potential access to hard-to-reach populations	Potential privacy concerns/ethical issues
Fast data collection	Rapidly changing environment
Potentially less burdensome on the participant	Certain populations will be excluded if this is the only method
Can be cost effective	Data quality concerns
Easy to utilize partnerships and collaborations	Requires significant staff time to successfully engage and monitor

Cons

MUSC Medical University of South Carolina — South Carolina Clinical & Translational Research Institute

Community partnerships

- Should be long term, mutually beneficial relationship
    - Most effective when these relationships form before there is an ask
    - Refrain from "helicopter in, then leave"
    - Long-standing relationship often makes study team a trusted source (not dependent on community champions alone)
- Ask, don't assume, what the incentive is for the individuals/organizations
- Ideal when they can offer feedback on study design but, at minimum, should be allowed to offer insight on recruitment strategies and messaging

MUSC Medical University of South Carolina | South Carolina Clinical & Translational Research Institute

---

TRACK to make sure the juice is worth the squeeze!

- Must determine how you will define "success" of each strategy
    - Some strategies might be less about individual study recruitment and more about community trust building or continued engagement
        - Set recurring times to assess if the resources used are yielding desired results
- Looking to see if you are getting the RIGHT people
    - Strategies can yield high response rates but poor candidates for the study, thus decreasing efficiency (they don't pass screen, consistently no shows, etc.)
    - Are you getting the representation you need? Is a demographic group missing?
- Incorporate ways early on to capture how people heard about the study
- If you have multiple messages for a particular strategy, find ways to identify which was seen
- Some strategies may ebb and flow in success

MUSC Medical University of South Carolina | South Carolina Clinical & Translational Research Institute

What I Wish I Knew: Top Recruitment Insights from a new CRC

❖ Getting familiar with study and Identifying study gaps
❖ Adapting Recruitment Strategies Based on Feedback
  ❖ Building Relationships within the Community
    ❖ Tailoring Communication to Participants
❖ Leveraging Institutional and National Resources

UF | College of Medicine
UNIVERSITY *of* FLORIDA

---

1. Getting familiar with study and Identifying study gaps

Key Insight: Taking time to understand the protocol fully helps in anticipating participant needs.

Lesson Learned: Knowing the study design prevented protocol deviations early on.

2. Adapting Recruitment Strategies Based on Feedback

Key Insight:
Participant feedback shapes recruitment methods.

Lesson Learned:
Adjusting materials and language increased engagement.

3. Building Relationships within the Community

Key Insight: Community trust drives successful recruitment.

Lesson Learned: Local events and engagement strengthen connections.

UF | College of Medicine
UNIVERSITY *of* FLORIDA

4. Tailoring Communication to Participants

Key Insight: Effective communication varies by participant background.

Lesson Learned: Language and tone adjustments improve participant understanding.

5. Leveraging Institutional and National Resources

ClinicalTrials.gov

UF | Clinical and Translational Science Institute UNIVERSITY *of* FLORIDA

HEALTHSTREET UNIVERSITY *of* FLORIDA

rn researchmatch.org
Difficult diseases have met their match.

Key Insight: Existing resources can significantly support recruitment.

Lesson Learned: Institutional databases and partnerships make recruitment more efficient

UF | College of Medicine UNIVERSITY *of* FLORIDA

Breakout session: let's chat CHALLENGES

- Group members will describe an experience when they/they're study team faced significant recruitment challenges
  - What ways did you try to overcome the challenge?
- Have others in the group had a similar experience? What resources or strategies were used when trying to find a solution?
- If you or other members of the group don't have your own solutions to share from experience, brainstorm amongst one another how some of the information learned in this presentation might inform potential solutions/strategies.
- Please be prepared for a member of your group to present a summary of your discussion to the larger group. Tara and Shravani will help you find solutions and resources for any lingering challenges your group may have.

Where can we go from here?

Tools and resources to guide you on your recruitment journey

Slide 1

Leveraging institutional resources

- CTSA support services (free and fee based)
  - Guidance and tools for identifying your population, strategy development and message creation
  - Many facilitate and/or manage EHR recruitment initiatives
  - Social media accounts and/or campaign development
- Institutional clinical trials directories and/or patient registries
- Marketing/Communications team for content development support or social media opportunities

UF | Clinical and Translational Science Institute
UNIVERSITY of FLORIDA

MUSC Medical University of South Carolina
South Carolina Clinical & Translational Research Institute

Slide 2

research match.org
Difficult diseases have met their match.

| Volunteers create profiles with demographic and health info | Researchers send study information to an unidentified group of patients that match specified criteria | If a volunteer reads study message and replies they're interested, their contact info is released to the researcher |

- A free 'matching' tool, built and maintained by Vanderbilt to help volunteers easily connect with research studies
- An innovative national partnership to develop a centralized web-based recruitment registry
- Researchers can use feasibility component to consider implementation

UF | Clinical and Translational Science Institute
UNIVERSITY of FLORIDA

MUSC Medical University of South Carolina
South Carolina Clinical & Translational Research Institute

Recruitment Innovation Center (RIC) resources

- The RIC is part of a larger CTSA program initiative, known as the Trial Innovation Network (TIN) designed to address major roadblocks in clinical research through collaboration and innovation

- Share evidence-based trial recruitment tools and strategies

- TIN toolbox- free resources for study design and conduct compiled of submissions from CTSAs and reputable sources and provides them as a free resource to the research community.
    - Can filter by recruitment-related resources or by RIC-developed resource

- RIC Community of Practice- social space for research staff engaging in recruitment to ask questions, share resources and contribute knowledge about best practices

- Consultative services: recruitment planning, material development, EHR cohort analysis

UF Clinical and Translational Science Institute
UNIVERSITY *of* FLORIDA

MUSC Medical University of South Carolina | South Carolina Clinical & Translational Research Institute

---

Join the RIC Community of Practice today!

[QR code]

UF Clinical and Translational Science Institute
UNIVERSITY *of* FLORIDA

Thank you!

Tara Pittman, abbottt@musc.edu, 843-792-2926

Shravani Chobhe, Shravani.Chobhe@neurology.ufl.edu

MUSC Medical University of South Carolina | South Carolina Clinical & Translational Research Institute

MUSC recruitment resources

- SCTR's website: sctr.musc.edu
  - Learn more about the resources (including and beyond recruitment), training and funding opportunities offered through our CTSA
- All recruitment consultation resources can be found in SPARC (sparc.musc.edu) under "SUCCESS Center"
  - Includes recruitment, integrating special populations, Patient Outreach Recruitment (cold-contact), ResearchMatch support, etc.
- Patient Outreach Recruitment (cold contact) researcher resource website
  - Learn more about MUSC's opt-out policy for research contact and our guidelines for implementation of cold-contact recruitment for patients identified via the EHR

SUCCESS Center

The SUCCESS Center offers a number of free consultative services in effort to provide education, training, and mentoring related to all phases of the research process.

- ▶ Drug Management Services
- ▶ Grant Forms & Budget Services
- ▶ Patient Outreach Recruitment (cold-contact)
- ▶ Recruitment Services
- ▶ Regulatory Services
- ▶ Research Advertising on Social Media
- ▶ Research Navigation Services
- ▶ Special Populations Navigation

MUSC
Medical University of South Carolina

South Carolina
Clinical & Translational
Research Institute

University of Florida CTSI recruitment resources

- HealthStreet
  - Community engagement and recruitment service that connects researchers with potential participants.
  - Offers no-cost consultation and feasibility analysis for study recruitment.
- Community Outreach Tools
  - Tools like IDR, i2b2, and Consent2Share are utilized for recruiting participants based on UF's data networks.
  - Community Outreach Tools - UF CTSI
- UF CTSI Support Services
  - Provides consultations on recruitment strategies, participant engagement, and feasibility assessments.

UF | Clinical and Translational Science Institute
UNIVERSITY of FLORIDA

Recruitment Center

Research Services Overview
- Pilot Funding
- Voucher Request
- Research Navigation and Regulatory Assistance
- Research Design and Data Coordinating Center
- Data, Informatics and IT
- Recruitment Center
  - Recruitment Consultations
  - Social Media Recruitment
  - ResearchMatch
- Recruitment Flyers

UF CTSI
Recruitment Center
The CTSI Recruitment Center optimizes recruitment and retention of study participants through consultations and services and collaborative research on the science of recruitment.

REQUEST A CONSULTATION →

UF | Clinical and Translational
Science Institute
UNIVERSITY of FLORIDA