Journal of Clinical and Translational Science

www.cambridge.org/cts

Education Perspective

Cite this article: Cook SK, Kennedy N, Boone L, Drury B, Rodweller C, Stroud M, Nelson SJ, Edwards T, Wilkins CH, and Harris P. What we wish every investigator knew: Top 4 recruitment and retention recommendations from the Recruitment Innovation Center. *Journal of Clinical and Translational Science* **6**: e31, 1–4. doi: 10.1017/cts.2022.370

Received: 2 December 2021
Revised: 31 January 2022
Accepted: 21 February 2022

Address for correspondence:
S. K. Cook, MPH, Vanderbilt Institute for Clinical and Translational Research, Vanderbilt University Medical Center, 2525 West End Avenue, Suite 600, Nashville, TN 37203, USA.
Email: sarah.k.cook@vumc.org

What we wish every investigator knew: Top 4 recruitment and retention recommendations from the Recruitment Innovation Center

Sarah K. Cook[1], Nan Kennedy[1], Leslie Boone[1], Bethany Drury[1], Casey Rodweller[1], Mary Stroud[1], Sarah J. Nelson[1], Terri Edwards[1], Consuelo H. Wilkins[1,2,3,4] and Paul Harris[1,5]

[1]Vanderbilt Institute for Clinical and Translational Research, Vanderbilt University Medical Center, Nashville, TN, USA; [2]Department of Medicine, Vanderbilt University Medical Center, Nashville, TN, USA; [3]Department of Internal Medicine, Meharry Medical College, Nashville, TN, USA; [4]Office of Health Equity, Vanderbilt University Medical Center, Nashville, TN, USA and [5]Department of Biomedical Informatics, Vanderbilt University Medical Center, Nashville, TN, USA

Worldwide, 90% of clinical trials suffer from slower-than-expected enrollment [1] and roughly one in five studies terminate early or settle for a smaller total sample size than desired [2]. Moreover, under-enrollment of racial and ethnic minority populations is endemic – the Food and Drug Administration reports that 75% of participants in drug therapeutic trials are white [3], while 40% of the US population identifies as a racial or ethnic minority [4]. Poor recruitment and retention performance are costly to researchers and sponsors and detrimental to public health when advances fail to materialize or do not benefit all [5].

The Recruitment Innovation Centre (RIC) [6], part of the Trial Innovation Network's collaborative initiative within the Clinical and Translational Science Award (CTSA) Program, is tasked with addressing critical roadblocks in clinical research [7]. The RIC consults with CTSA hubs and their research teams on strategies to increase clinical trial enrollment by developing, testing, and sharing innovations to enhance participant recruitment and retention. After 220 consultations with investigators nationwide, the RIC has compiled four primary recommendations for addressing common pitfalls in recruitment and retention (Fig. 1). These recommendations were determined by consensus among eight RIC consultants after evaluating common challenges described by investigators during their recruitment consultations.

Recommendations

Recommendation #1: Proactively assess recruitment and retention barriers and develop mitigation strategies

Investigators often fail to plan and prepare for recruitment and retention issues that can significantly impact the success of their clinical trial. Once embarked on recruitment, researchers can encounter unanticipated challenges. An important first step of any clinical trial is to proactively identify potential obstacles based on previous experience, trial-specific details, and characteristics of the target population. Once barriers have been ascertained, study teams should develop a remediation plan before beginning enrollment.

A risk assessment planner can be a helpful tool. The RIC-developed ***Risk Register*** [8] assists investigators to identify possible risks, appraises the likelihood that these risks will occur, and evaluates the potential impact on the trial. Study teams use this assessment to calculate a subjective "risk score" ranging from 2 to 10, with higher scores indicating greater risks to recruitment and retention. Risk scores can then be used to help prioritize decisions to mitigate barriers and minimize their impact. Table 1 illustrates potential barriers, associated risk scores, and recommended mitigation strategies for an example study.

In addition to proactively identifying risks, study teams should consider using the RIC-developed ***Recruitment and Retention Plan Template*** [8] to further delineate recruitment and retention strategies that can be used throughout the life of the trial.

Recommendation #2: Prioritize the participant journey: Minimizing burden and returning value

The needs and preferences of research participants are often overlooked or not fully considered when designing clinical trials. Unnecessarily burdensome study visits, inadequate reimbursement for costs of participating and not returning study results or other information of value to participants can contribute to lackluster study enrollment and high attrition. Strategies that focus on the participants include:

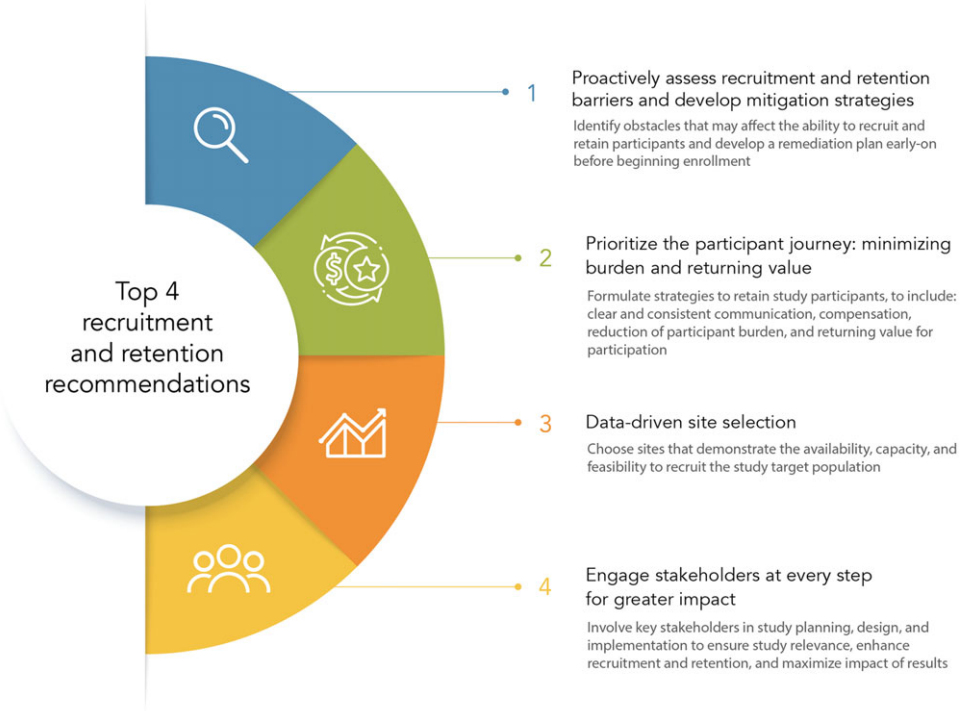

Fig. 1. The top four recruitment and retention recommendations from the Recruitment Innovation Center.

Clear, consistent, and timely communication. The manner and type of information shared with potential participants is critical to influencing participation. A clear plan for communicating study expectations during the enrollment phase and throughout study duration may ease anxiety about participation and demystify the trial experience. Study materials and communication should aim to be engaging and understandable across a wide range of literacy levels.

Adequate compensation. Study teams should compensate volunteers as a way of honoring the time and effort they are contributing to the study and help offset any costs to participating.

Reduction of participant burden. Study design and implementation may unintentionally create barriers that hinder participation. Researchers should map out the participant journey to identify unnecessary or overly burdensome procedures that can be minimized or eliminated.

Return of value for participation. Investigators should acknowledge volunteers' contributions and provide value to research participants. This should go beyond participant compensation and could include an array of benefits, such as returning study findings to participants, connecting them with others in the same disease community [12], and acknowledging their contributions in manuscripts, presentations, and other dissemination activities.

Recommendation #3: Data-driven site selection

When selecting sites for a multicenter clinical trial, investigators often choose sites where there are known colleagues, previous collaborations, or other personal preferences. To locate the strongest sites, however, investigators should use an informed approach that utilizes multiple sources of both quantitative and qualitative data.

Investigators should evaluate the availability of the target population to be recruited at each site. Electronic health record (EHR) data can be analyzed to determine whether an appropriate volume of patients with the specified health condition exists at a potential site [13]. Other data sources can be leveraged to assist in site identification and selection, including public health datasets and population-level data. Next, investigators should confirm each site possesses the resources and capacity to recruit and enroll the target participant demographics. These resources may include adequate effort allocation for research staff, proper equipment, and expertise in recruiting diverse populations.

Recruitment feasibility assessments for candidate sites should also include the evaluation of competing trials in similar medical domains. These trials may be vying for the same patient population or competing for a clinician's time, staff, or site resources. Information from ClinicalTrials.gov [14], including details on study phase, expected enrollment dates, and participating sites, can be paired with site-reported patient estimates to help identify risks and proactively inform remediation strategies. This could include investigators collaborating with other study teams on recruitment strategies that might benefit both trials.

Recommendation #4: Engage stakeholders at every step for greater impact

Stakeholder engagement has long been encouraged in clinical trials to ensure study relevance, enhance recruitment and retention, and maximize the impact of results [15]. Study teams, however, are often unaware of how best to engage key stakeholders or understand how doing so can contribute to their clinical trial in a meaningful way.

Research stakeholders are individuals, groups, and organizations that have a stake, interest, or could be affected by the conduct and results of a research study. These may include community members, patients, community-based organizations, and advocacy groups, as well as health care providers and clinicians. Research teams can involve key stakeholders in the planning, design, and

https://doi.org/10.1017/cts.2022.370 Published online by Cambridge University Press

Table 1. *Examples of recruitment barriers, risk assessment, and mitigation strategies*

Identified barrier	Recruitment and retention risk assessment: Probability of occurring (1–5 scale)	Impact (1–5 scale)	Calculated risk score (probability + impact) (2–10 scale)	Mitigation strategies
Investigator barriers				
Insufficient budget for recruitment and retention activities	3	3	6	**Include costs for all elements of recruitment and retention in the budget**, such as participant compensation, printing of materials, postage, etc.
Referring providers do not support the study	3	5	8	**Hold webinars with participating sites** to create interest among providers and to address their concerns about referring patients to the study.
Study teams have difficulty meeting screening and enrollment goals	3	5	8	**Actively engage and support study teams** across sites through regular communication and recurring calls. **Use incentives and "gamification" strategies** to encourage participation from research staff and healthy competition between the sites.
Study personnel unavailable during nonstandard working hours (cannot accommodate nights and weekends)	3	3	6	**Use REDCap** (research electronic data capture) [10,11] to offer remote assessments or to streamline on-site data collection. **Compensate participants** to reduce study burden due to potential lost wages.
Participant barriers				
Overly burdensome study activities	3	4	7	**Provide step-wise compensation** and other 'return of value' initiatives throughout participation to help ensure continued engagement and retention.
Lack of culturally appropriate outreach to underrepresented minority populations, including non-English speakers	3	3	6	Have study teams **take the *FasterTogether* course** [9] to increase knowledge of methods to reach underrepresented populations. **Obtain feedback on recruitment messaging** from underrepresented and minority groups. **Translate participant-facing materials** into other languages commonly spoken by the target study demographic.
Study involves a placebo or "sham" group that may be confusing to or perceived as an unattractive option by research participants	4	3	7	Have study coordinators hold discussions and **provide educational materials for participants on rationale for randomization**. Consider **offering access to active intervention** among those randomized to placebo group after conclusion of study.

Probability of Risk Occurring ranges from 1 (Rare) to 5 (Highly Probable); *Impact of Risk* ranges from 1 (Very low) to 5 (Very high); Calculated *Risk Score* ranges from 2–3 (Accept the risk), 4–6 (Mitigate the risk), 7–8 (Transfer the risk), to 9–10 (Avoid the risk).

implementation of their study by collecting and integrating their feedback [16]. Helpful methods may include:

- Obtaining input on recruitment strategies, materials, and messaging from members of the target study population, such as through a community engagement studio [17–19]
- Forming a Community Advisory Board that includes representatives from diverse communities to give feedback on recruitment and retention methods to increase the representation of underrepresented groups [20,21]
- Partnering with trusted local and national community organizations to raise awareness of the trial among diverse populations [22,23]
- Building mutually beneficial relationships with health care providers and requesting their assistance in patient referrals [24]
- Acknowledging community stakeholders and partners in scientific manuscripts and dissemination activities or including them as co-authors

Resources

Enrolling and retaining a sufficient, representative participant population for clinical trials can be challenging. The four primary recommendations presented in this paper represent a consensus of opinion among eight RIC consultants, gleaned from several years of consultation experience with study teams. A more detailed account of the RIC's consultations, recruitment resource implementation, and resource evaluation plans has been previously reported on [6]. Investigators can obtain assistance in incorporating these recommendations by accessing free tools and resources on the TIN website, through their local CTSA liaisons, or by submitting a proposal request for a RIC consultation. Future evaluations of RIC resources will also be deposited in the TIN website for public access. Asking the right questions, documenting and prioritizing plans, following through, and monitoring and adjusting strategies as the study accrues participants is the most promising road to recruitment success.

https://doi.org/10.1017/cts.2022.370 Published online by Cambridge University Press

Disclosures. The authors have no conflicts of interest to disclose.

References

1. **Institute of Medicine (US) Forum on Drug Discovery D**. *The State of Clinical Research in the United States: An Overview*. Washington, DC: National Academies Press, 2010.
2. **Carlisle B, Kimmelman J, Ramsay T, MacKinnon N.** Unsuccessful trial accrual and human subjects protections: an empirical analysis of recently closed trials. *Clinical Trials* 2015; **12**(1): 77–83. DOI 10.1177/1740774514558307.
3. 2020 Drug Trials Snapshots Summary Report. 2020: 15.
4. **United States Census Bureau. Quick Facts**. (https://www.census.gov/quickfacts/fact/table/US/PST045219).
5. **Huang GD, Bull J, Johnston McKee K, Mahon E, Harper B, Roberts JN.** Clinical trials recruitment planning: a proposed framework from the Clinical Trials Transformation Initiative. *Contemporary Clinical Trials* 2018; **66**: 74–79. DOI 10.1016/j.cct.2018.01.003.
6. **Wilkins CH, Edwards TL, Stroud M**, ***et al.*** The Recruitment Innovation Center: developing novel, person-centered strategies for clinical trial recruitment and retention. *Journal of Clinical and Translational Science* 2021; **5**(1): 35. DOI 10.1017/cts.2021.841.
7. **Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG.** Research electronic data capture (REDCap)—a metadata-driven methodology and workflow process for providing translational research informatics support. *Journal of Biomedical Informatics* 2009; **42**: 377–381.
8. **Recruitment & Retention Plan Template**. Trial Innovation Network Toolkit. (https://trialinnovationnetwork.org/material-details/?ID=140).
9. **Kusnoor SV, Villalta-Gil V, Michaels M**, ***et al.*** Design and implementation of a massive open online course on enhancing the recruitment of minorities in clinical trials - Faster Together. *BMC Medical Research Methodology* 2021; **21**(1): 44. DOI 10.1186/s12874-021-01240-x.
10. **Harris PA, Taylor R, Minor BL**, ***et al.*** The REDCap consortium: building an international community of software platform partners. *Journal of Biomedical Informatics* 2019; **95**: 103208.
11. **Bernard GR, Harris PA, Pulley JM**, ***et al.*** A collaborative, academic approach to optimizing the national clinical research infrastructure: the first year of the Trial Innovation Network. *Journal of Clinical and Translational Science* 2018; **2**(4): 187–192. https://dx.doi.org/10.1017%2Fcts.2018.319
12. **Wilkins CH, Mapes BM, Jerome RN, Villalta-Gil V, Pulley GM, Harris PH.** Understanding what information is valued by research participants, and why. *Health Affairs* 2019; **38**(3): 399–407. DOI 10.1377/hlthaff.2018.05046.
13. **Nelson SJ, Drury B, Hood D**, ***et al.*** EHR-based cohort assessment for multicenter RCTs: a fast and flexible model for identifying potential study sites. *Journal of the American Medical Informatics Association* 2021; **383**(15): 1406. DOI 10.1093/jamia/ocab265.
14. **ClinicalTrialsgov**. *NIH US National Library of Medicine*. (https://clinicaltrials.gov/).
15. **De las Nueces D, Hacker K, DiGirolamo A, Hicks LS.** A systematic review of community-based participatory research to enhance clinical trials in racial and ethnic minority groups. *Health Services Research* 2012; **47**(3 Pt 2): 1363–1386. DOI 10.1111/j.1475-6773.2012.01386.x.
16. **Boyer AP, Fair AM, Joosten YJ**, ***et al.*** A multi-level approach to stakeholder engagement in the formulation of a Clinical Data Research Network. *Medical Care* 2018; **56**(10 Suppl 1): S22–S26.
17. **Joosten YA, Israel TL, Williams NA**, ***et al.*** Community engagement studios: a structured approach to obtaining meaningful input from stakeholders to inform research. *Academic Medicine* 2015; **90**(12): 1646–1650.
18. **Joosten YA, Israel TL, Head A**, ***et al.*** Enhancing translational researchers' ability to collaborate with community stakeholders: lessons from the community engagement studio. *Journal of Clinical and Translational Science* 2018; **2**(4): 201–207.
19. **Israel T, Farrow H, Joosten Y, Vaughn Y.** *Community Engagement Studio Toolkit 2.0*. (https://trialinnovationnetwork.org/material-details/?ID=98).
20. **Newman SD, Andrews JO, Magwood GS, Jenkins C, Cox MJ, Williamson DC.** Peer reviewed: community advisory boards in community-based participatory research: a synthesis of best processes. *Preventing Chronic Disease* 2011; **8**(3).
21. **Kubicek K, Robles M.** *Resource for integrating community voices into a research study: community advisory board toolkit*. Southern California Clinical and Translational Science Institute, 2016. (https://trialinnovationnetwork.org/material-details/?ID=132).
22. **Michaels M.** *Community Outreach Guide*, 2019. (https://trialinnovationnetwork.org/material-details/?ID=86).
23. *Toolkit for Developing Community Partnerships. Southern California Clinical and Translational Science*. (https://trialinnovationnetwork.org/material-details/?ID=145).
24. **Michaels M.** *Referring Providers Outreach Guide*, 2019. (https://trialinnovationnetwork.org/material-details/?ID=85).

https://doi.org/10.1017/cts.2022.370 Published online by Cambridge University Press