

**RESEARCH LETTER****Recommendations for using the 5Ts Framework to support research inclusion across the lifespan**

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**INTRODUCTION**

Older adults are often underrepresented in research studies, which results in evidence that is not relevant to those who experience the greatest burden of disease.<sup>1-3</sup> Underrepresentation of older adults commonly occurs when studies have strict exclusion criteria, and when studies fail to address barriers to participation.<sup>2,3</sup> Inclusion rates are even lower for older adults from diverse racial and ethnic groups and those from rural communities, likely related to the intersectionality effects of older age with race, ethnicity, and geography.<sup>4-6</sup>

The 5Ts Framework was developed to support inclusion of diverse populations of older adults in research and facilitate implementation of the National Institutes of Health (NIH) Inclusion Across the Lifespan Policy.<sup>7</sup> The

framework is designed to help research teams remember five important factors to consider: target population, team, time, tips to accommodate, and tools.<sup>1</sup>

Initial development of the 5Ts Framework had limited input from research partners and community members. The purpose of this work was to elicit additional input on barriers and strategies for inclusion to expand the range of input informing the framework and subsequent list of recommendations.

**METHODS**

We convened eight Community Engagement Studios (CES) between October 2019 and December 2021, across two institutions, Duke University and Oregon Health &

Science University (OHSU).<sup>8</sup> In each 1.5–2 h CES, the 5Ts Framework guided a discussion around research inclusion challenges, and strategies to address identified challenges. Each CES had a designated note-taker. Verbatim transcriptions were not generated.

We intentionally sought input from diverse and intersectional groups including older adults, research personnel, community experts, Black or African American persons, Hispanic or Latino/Latina/Latinx persons, and those living in rural areas (see Supplemental Materials).

Rapid qualitative analysis, a valid and rigorous methodology for the purpose of broadening understanding on a shorter timeline,<sup>9</sup> was conducted based on detailed notes. This analysis confirmed a priori identified 5Ts themes as outlined in the framework (Figure 1), as well as broader themes across all Ts. We then used matrix analysis to categorize findings by informant type (research personnel, research participant).

## RESULTS

Across the 5Ts, three broad themes arose for *research personnel*. The first centered around *research processes challenges*, which included those related to research infrastructure, such as lack of support systems or training. We heard from many research personnel that they learn to recruit older adults through trial and error, without any guidance or training.

*Research protocol challenges* was a second theme that came up. This included challenges that are study-specific, and often arise during the life of a study. One example was that older adult participation is influenced by transportation barriers. Collaborating with community

organizations is one way that was discussed to practically address this study-specific challenge.

Lastly, we heard about *institutional and cultural challenges*, which arose when participants had limited or negative experience with research. Research personnel noted that a key component of addressing this institutional challenge was establishing and fostering trust through creating long-term community partnerships, listening and adjusting to participant needs, and sharing aggregate study results.

Three broad themes arose for *research participants*, spanning across the 5Ts. The first theme centered around *enhancing motivation to participate*. We heard that research participants were motivated by personal reasons to participate. Many expressed that motivation stemmed from the perceived benefit to their community.

*Decreasing burden to participate* was a second theme that came up. We heard that participation is largely based on personal circumstances, and the potential inconvenience or burden involved in participating. Older adult participants expressed weighing their motivation against the impact on their lives when considering whether to participate.

Lastly, we heard from research participants about the importance of *fostering trusting relationships* to facilitate research engagement and participation. Research participants noted that establishing trust is essential and takes time, intentional relationship building, and listening skills. All findings are included in Table 1.

## DISCUSSION

Our results highlight broad themes we heard from research personnel and research participants, providing a general structure for study teams to better understand where they may need to focus their efforts to be more

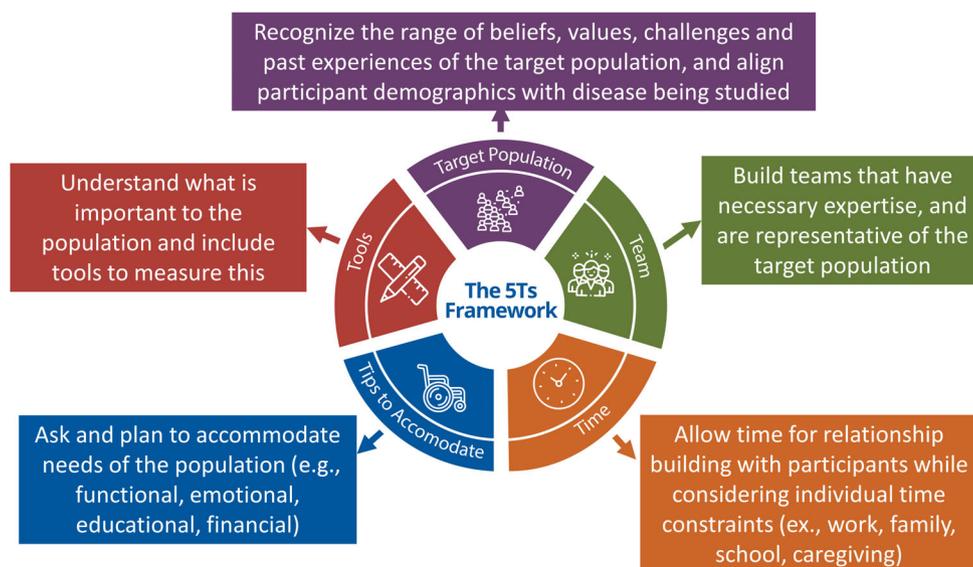


FIGURE 1 Incorporating community perspectives into the 5Ts Framework.

TABLE 1 Key findings and recommendations from engagement of research personnel and research participants.<sup>a</sup>

Research personnel		Research participants	
5T	Findings	Practical recommendations for study team	Findings
Target population	<ul style="list-style-type: none"> <li>• Study populations are often not representative of real-world populations</li> <li>• Participants may have limited or negative experience and/or education about clinical research</li> </ul>	<ul style="list-style-type: none"> <li>• Ensure study team, activities, and materials are inclusive and representative of the population you are trying to reach</li> <li>• Educate participants, caregivers, and communities about clinical research by sharing positive experiences, study results, and how results will be used</li> </ul>	<ul style="list-style-type: none"> <li>• Communities may have different interpretations of research terms (e.g., the word “Target” population)</li> </ul>
Team	<ul style="list-style-type: none"> <li>• Research teams do not prepare for challenges to recruiting older adults</li> <li>• Research staff learn to recruit older adults through trial and error and have limited opportunities to learn from others’ success</li> <li>• Family and caregiver relationships are important in research involvement</li> <li>• Study teams should be knowledgeable and reflective of the African American community and/or Latinx community</li> <li>• Language can be a barrier to participation</li> </ul>	<ul style="list-style-type: none"> <li>• Use 5Ts during study kick-off meeting to anticipate/plan for challenges, and revisit at key phases of the study (e.g., prior to enrollment)</li> <li>• Provide opportunities for research staff to share challenges and successes with other study teams</li> <li>• Consider the broader “team” of research participants (e.g., their caregiver, children, other family members) and encourage them to accompany participants when appropriate</li> <li>• Engage community partners and health care professionals to incorporate community members reflective of the study population to serve as trusted liaisons between participants and the research team</li> <li>• Include team members who speak the language(s) of the study population, or have interpreters available</li> </ul>	<ul style="list-style-type: none"> <li>• Family and caregiver relationships are important in research involvement</li> <li>• Study teams should be knowledgeable and reflective of the African American community and/or LatinX community</li> <li>• Consider the broader “team” of research participants (e.g., their caregiver, children, other family members) and encourage them to accompany participants when appropriate</li> <li>• Engage community partners and health care professionals to incorporate community members reflective of the study population to serve as trusted liaisons between participants and the research team</li> </ul>

(Continues)

TABLE 1 (Continued)

Research personnel		Research participants	
5T	Findings	Practical recommendations for study team	Findings
Time	<ul style="list-style-type: none"> <li>• Time and listening skills are required to build trust</li> <li>• Establishing long-term partnerships is an important component of successful recruitment</li> </ul>	<ul style="list-style-type: none"> <li>• Plan for and budget adequate time to educate potential participants and their families about the study</li> <li>• Continue to engage with study population, their families and the groups that serve them beyond clinical settings and after study completion</li> </ul>	<ul style="list-style-type: none"> <li>• Establishing trust is important for successful recruitment</li> <li>• Plan for and budget adequate time to educate potential participants and their families about the study</li> </ul>
Tips to accommodate	<ul style="list-style-type: none"> <li>• Use of technology and the level/amounts of information shared can exclude participants</li> <li>• Participation can be influenced by lack of SSN</li> <li>• Participation is influenced by language</li> <li>• Participation is influenced by transportation barriers</li> </ul>	<ul style="list-style-type: none"> <li>• Design study to accommodate a variety of engagement methods</li> <li>• Consider the needs and preferences when planning incentives</li> <li>• Translate study materials into the native language(s) of the target audience</li> <li>• Collaborate with community organizations to address transportation barriers</li> </ul>	<ul style="list-style-type: none"> <li>• Study participation is influenced by individual motivations and inconveniences or burdens</li> <li>• Participation is strongly influenced by relevance and benefits for the larger community</li> <li>• Ask about anticipated inconveniences and preferences, and communicate possible accommodations</li> <li>• Design study materials and messaging to emphasize study benefits to larger community</li> </ul>
Tools	<ul style="list-style-type: none"> <li>• There is an opportunity to better assess and understand the social determinants of health (SDOH) of participants</li> <li>• Aggregate study results can be shared with participants as one way to build trust</li> </ul>	<ul style="list-style-type: none"> <li>• Assess social determinants of health early in the study, and provide accommodations as relevant/able</li> <li>• Utilize a structured method or tool for organizing and sharing study results with participants</li> </ul>	

\*Findings from eight Community Engagement Studios conducted between October 2019 and December 2021 at Duke University and Oregon Health & Science University.

inclusive of older adults. In addition, findings provided support for the 5Ts Framework as a valuable strategy to anticipate barriers to research participation, and identify strategies to overcome them. The 5Ts Framework may complement existing efforts to make research more inclusive of older adults by providing a practical tool.<sup>7,10</sup>

It is essential to close the gap between real-world prevalence and research participation. Failure to include older, diverse populations in research results in an evidence-base that is not equitable and prevents us from meeting the needs of those who experience the greatest burden of disease.

### AUTHOR CONTRIBUTIONS

Authors contributed to the conceptualization, drafting, and revising the manuscript, and provided final approval.

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### CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest.

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The sponsors were not involved in the design, methods, data collection, or analysis of the study and had no role in the preparation of the manuscript.

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### SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

**Supplemental Table 1:** Description of Community Engagement Studios between October 2019 and December 2021 at Duke University and Oregon Health & Science University.

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