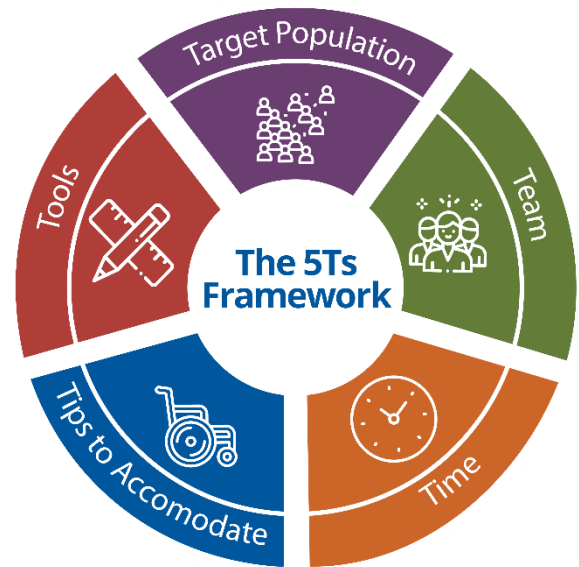


5Ts Framework to support inclusion of older adults in research

Problem: Underrepresentation of older adults in clinical research results in evidence that is not generalizable to those who experience the greatest burden of disease.

Urgency: The NIH “Inclusion Across the Lifespan” policy began in January 2019 and requires more rigorous approaches to including older adults. Experts in the field of aging research have experience recruiting and retaining older adults in clinical research, but a systematic approach to prepare for and address the challenges of inclusion of older adults does not exist outside of geriatrics. We have found that non-geriatrician investigators often lack the following: 1) knowledge about key concepts and available tools in aging research, 2) flexibility in study structures to accommodate older participants, and 3) an understanding of how to balance the need for generalizability of findings with the desire to focus on disease-specific effects.



The 5Ts Solution: The 5Ts framework describes maximizing generalizability by enrolling participants from the *Target population*, building research *Teams* that include geriatrics and gerontology expertise, incorporating appropriate *Tools* to measure function and patient-reported outcomes, anticipating *Time* for longer study visits, and accommodating older participants with comorbidities and age-related impairments by following practical *Tips*. This framework was developed to help:

- *Research Investigators* better anticipate challenges to inclusion of older adults, identify solutions, and address the NIH Lifespan policy
- *Research Teams* develop a checklist for operationalizing study protocols and, when appropriate, identify the need for additional expertise
- *Research Institutions* organize and deliver needed resources to support investigators

5Ts Recommendations: The 5Ts recommendations for maximizing inclusion across the lifespan were developed over multiple iterations by 1) eliciting expert advice from aging researchers, 2) conducting stakeholder interviews and group discussions that included research investigators, research staff, and older adults, and 3) reviewing existing literature on best practices for inclusion of older adults in research. Using this approach, recommendations were categorized the most relevant T to limit redundant recommendations. However, we recognize that some recommendations have relevance for more than one category. Efforts were made to limit recommendations to those that address the unique challenges of inclusion of older adults and should complement existing resources designed to maximize general study recruitment.

We define *Target population* as the “at risk” or “real-world” population and we recommend avoiding exclusions that intentionally or unintentionally limit participation by older adults from the target population. *Team* is defined broadly to include the research team as well as representation from the participant, family, community, and health care partners. *Time* includes the research team time, the pace of study tasks, and the overall time burden on participants. *Tips to accommodate* include best practices to support recruitment, retention, and meaningful

participation. *Tools* include instruments, devices, aids, or study materials, that are tangible and for which examples could be shared across studies.

5Ts Recommendations to Maximize Inclusion Across the Lifespan

Target Population (*“At risk” or “real-world” population*)

- Avoid exclusion criteria that limit study generalizability
- Provide scientific justification for upper age cut-offs or exclusion criteria that disproportionately affect older adults
- Know the prevalence and incidence of the studied condition in older adults
- Know the demographics of the target population and geographic area with regards to average age, age range, gender, race, and ethnicity
- Estimate the prevalence of sensory, functional, and cognitive limitations in the target population
- Estimate the prevalence of common, co-occurring chronic conditions in the target population
- Recognize the range of cultural and religious beliefs and preferred languages of members of the target population
- Understand common motivations for research participation including personal relevance of the study focus
- Understand concerns about participating in research among members of the target population

Team (*Representative teams that engage relevant stakeholders*)

- Engage experts in aging research at all stages of the study and to serve on safety monitoring boards
- Assemble study teams with experience and skills interacting with older participants at all study stages including recruitment, enrollment, data and specimen collection, or intervention delivery
- Train team members to recognize and accommodate age-related sensory, functional, and cognitive limitations
- Build culturally competent and inclusive research teams that include members of the target community
- Involve participants, their family, their caregivers, or their community advocates as active members of the team
- Engage participants’ health care providers, when appropriate, to allow them to advise their patients about study participation

Time (*Participant and study time*)

Be flexible with timing

- Work around the participant’s schedule or clinic visits
- Offer study visit times outside of normal business hours
- Be understanding about cancellations and setting up make-up appointments
- Be understanding that it may take longer to schedule follow-up visits as participants often require assistance from others for transportation and scheduling

- Allocate time for study staff to provide updates, reschedule missed visits, obtain missing study measures or devices (missing activity monitors, data collection diaries) and connect with participants who have had an acute health event requiring hospitalization or post-acute care in a skilled nursing facility

Set the right pace

- Plan for appropriate screening time and possible lower response rates
- Anticipate various literacy levels and familiarity with consent documents and allow adequate time to review written study materials
- Plan for initial time to educate participants about research in general before discussing the specific study procedures
- Allot enough time for decision making during the informed consent process and provide opportunities for participants to seek advice from family, caregivers, or their health care providers
- Anticipate longer study visits for some participants

Limit time requirements

- Limit the number study measures to only those necessary to address the study question
- Use the briefest study measures when possible to reduce participant fatigue
- Avoid adding study measures that address unplanned future research questions
- Balance the number of study visits versus the length of each study visits based on participant preferences

Tips to accommodate *(Suggestions to facilitate recruitment, retention, and meaningful participation)*

General tips

- Provide door-to-door transportation by contracting with local transportation vendors, providing cab vouchers, or arranging transportation using mobile ride-share services (budget for at least 15% of proposed study participants)
- Meet participants at the entrance and escort them to the study assessment area
- Identify study locations that are convenient for participants such as a community center, senior living facility, their local clinic, or locations with convenient parking
- Ensure study rooms are large enough to accommodate the participant, caregivers, assistive devices such as wheelchairs or scooters as well as research staff and study equipment
- Avoid transportation challenges by using telecommunication strategies including telephone surveys or video chat applications when possible
- Offer less burdensome opportunities for participants to contribute to the study by skipping a study visit or reducing the number of follow-up assessments if participants are considering withdrawing from the study
- Identify at least two contacts who could serve as proxy informants for participants who experience health events, functional decline, or illness during study follow-up that limits their ability to fully participate
- Consider caregiver needs including comfortable waiting areas, easy parking, or convenient drop off locations

- Use a single study telephone number to ensure participants can easily contact the study team
- Develop a clear, simple message to describe the study to help participants understand the purpose and their role in the study

Sensory, functional, and cognitive limitations

Hearing

- Ask about hearing difficulty or use of hearing aids
- Observe for signs of hearing difficulty such as asking for questions to be repeated, giving odd answers, or when interviewer can hear background noise or feedback
- Remind patients who use hearing aids to bring these to study visits or use during study telephone calls
- Use a standardized hearing protocol when hearing difficulties are identified (avoid using high pitch voice, speak clearly, move to a quiet room, reduce ambient sound, switch from cellphone to land line, relocate for better signal, using hearing aids or voice amplification devices)
- Have pocket-talkers or handheld hearing amplifiers available at study visits
- Reduce ambient noise during study visits by choosing a quiet room, avoiding areas with ongoing construction, and closing doors

Vision

- Ask about problems with vision, use of glasses, or difficulty reading small print
- Remind participants to bring reading glasses to study visits
- Use high-contrast written materials (black font/white background) and large font size
- Provide pictures of study medications and clearly identified bottles or packages with large font
- Choose location for study visits that have appropriate lighting and avoid areas with high glare including high-polished floors or reflected sunlight

Mobility limitations

- Ask about difficulty walking, climbing stairs, or use of mobility assistive devices including canes, walkers, wheelchairs or motorized scooters
- Remind participants to bring assistive devices to study visits
- Allow participants to complete some or all of the data collection from home using telephone surveys or web-based data collection
- Anticipate possible delays for participants to answer the telephone when calling land lines
- Choose study locations that are close to parking, do not require stairs, or long walking distances
- Have wheelchairs available for participants and their caregiver/family when escorting them to the study location
- Ensure there are railings and grab bars in study assessment or specimen collection areas including hallways or bathrooms

Functional limitations

- Ask about other limitations that might affect the participant's ability to complete study assessments or interventions including hand dexterity, bending or kneeling, transferring or endurance
- Address potential challenges to study specific activities such as opening pill bottles or medication blister packs, transferring from a chair to an examine table, or collecting specimens

Cognitive limitations

- Understand that slower recall or longer time to learn new information may be normal signs of aging and not cognitive impairment
- Recognize signs of cognitive impairment including poor memory, low comprehension, repeating statements, and inappropriate responses and distinguish these from other possible causes such as hearing loss or low educational attainment
- Determine if cognitive screening is necessary to identify participants with cognitive limitations
- Recognize that abnormal cognitive testing is not diagnostic for cognitive impairment or dementia and may result from low attention, distraction, hearing loss, low education, language barriers, or cultural biases in cognitive tests
- Send reminders to participants or and caregivers when cognitive limitations are present
- Consider use of proxies for data collection if cognitive limitations prior to enrollment and obtain permission to contact proxies if limitations develop during study follow-up
- Develop a protocol for assessing capacity to provide informed consent
- Consider the process for identifying legal authorized representatives among participants who cannot provide informed consent

Participants with chronic conditions

- Know that older participants often have multiple chronic conditions
- Understand the potential for adverse events related to other chronic conditions
- Ask participants about chronic conditions and the potential impact on proposed study procedures
- Recognize and address participant concerns about how participation may impact their other health conditions
- Advise participants whether or not to take regularly prescribed medications prior to attending study visits
- Provide participants with expected length of time away from home for the study visit including travel and encourage participants to bring necessary health care equipment or medications
- Provide participants with information to share with their healthcare providers

Tools (*Instruments, devices, aids, or study materials*)

Tools for recruitment and enrollment

- Create personalized recruitment materials when possible
- Written study timeline for participants and their caregivers

- FAQs sheet or “cheat sheet” with important study information for participants and their caregivers
- Participant folder with important study documents
- Consent documents that include pictures of study tasks
- Two versions of consent – one shortened, bulleted summary for easier reference
- Postage-paid envelope to return signed consent after review at home
- Proxy consent form template
- The University of California, San Diego Brief Assessment of Capacity to Consent (UBACC) 10-item scale to assess capacity to provide informed consent specific to clinical research
- Visible name tags for study staff with large print
- Electronic enrollment tracking system with capability to provide periodic enrollment reports by age

Tools for data collection and follow-up

- Visual aids for demonstrating study tasks or measures
- Data collection tools that allow multiple ways to enter data – online, tablet, paper, interviewer entered
- Modified assessments for in-home use
- Referral protocol for depression including warm hand-off to crisis prevention hotline or on-call mental health services
- Referral protocol for cognitive impairment or sudden changes in cognition that could be a sign of delirium
- Referral protocol for potential abuse or neglect

Measurement tools specific to older adults

Choose tools that measure function, physical performance, and patient-reported outcomes as appropriate. Adapted measures for hearing and vision limitations may be necessary.

- Mobility
- Functional status
- Physical performance measurement
- Physical activity
- Falls and balance
- Frailty
- Resilience
- Multimorbidity/comorbidity
- Cognition
- Delirium
- Depression
- Bladder or bowel function
- General health/quality of life
- Sleep
- Social support
- Caregiver responsibilities or caregiving received

- Hearing loss
- Visual impairment