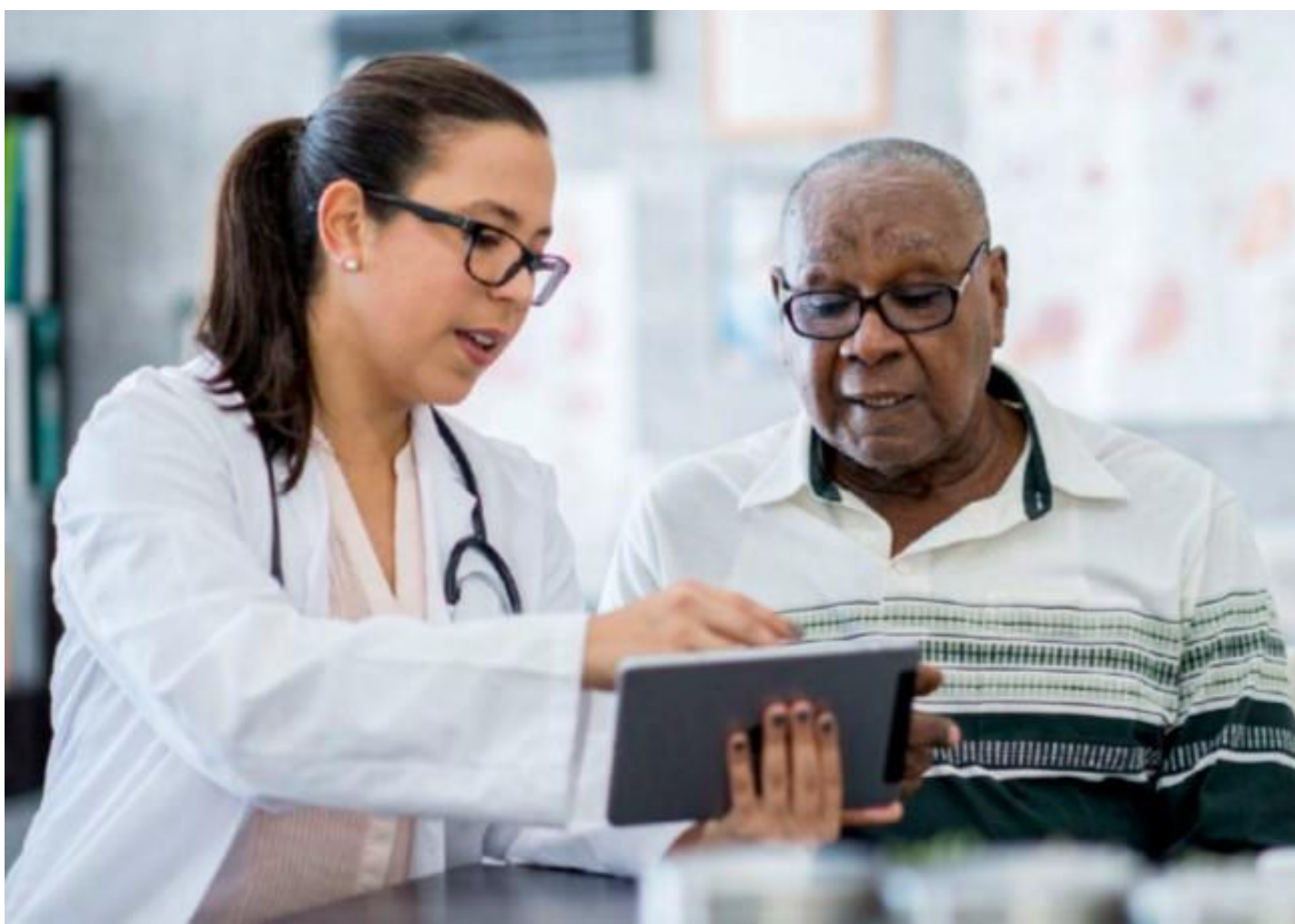# Older Adult Recruitment Resource Kit

A comprehensive kit of information, tools, and guidance materials to help in the recruitment and retention of older adults into research studies.

Contents

Inclusion of Older Adults in Research

There are more Americans age 65 and older today than any other time in history – about 49 million individuals.[1] 'Older adults', individuals aged 65 and over, is one of the fastest growing age groups in the U.S.[2] Though this population is growing fast, older adults are excluded from research at higher rates than other age groups. Many diseases are common in older adults, yet little research has been done with older ages.[3] In fact, research shows that across the major diseases for older adults, a large percentage of research performed in the U.S. is focused on a small percentage of the patient population, with a mismatch between participant age demographics and the age demographics of the disease being studied. Additionally, many diseases are distinctly different in older adults but research is limited in these age groups.[4]

This *Older Adult Recruitment Resource Kit* seeks to provide research teams with the information, tools, and guidance materials needed to help you recruit and retain older adults into your research studies. Thereby ensuring a better match between your participant demographics and disease demographics and compliance with the NIH Inclusion Across the Lifespan policy.[5]

1. National Institute on Aging: Strategic Directions for Research
2. U.S. Census Bureau: Older Population and Aging
3. Lockett et al. "Adequacy of Inclusion…"
4. Cherubini et al. "Fighting against Age Discrimination…"
5. NOT-OD-18-116: Inclusion Across the Lifespan

1. Age-Friendly Research Checklist

How to use this tool

This tool provides research teams with a list of considerations for their study to ensure it is age-friendly, including study design and procedures.

Checklist

Age-Friendly Research Checklist

- Match demographics of disease with study participants
  - Age range
  - Comorbidities do not exclude participants
- Use Age-Friendly language and communication
  - See Age-Friendly Communication Guidance document
- Adapt study for older adult impairments
  - Sensory impairment: pocket talker, larger font
  - Mobility impairment: home visits, wheelchair for research site visits, attending to risk for falls, orthostatic hypotension for drug/device/intervention studies
  - Cognitive impairment: consent form with capacity questions, legally authorized representative
- Accommodate older adult challenges
  - Allow extra time to complete visits
  - Extend data collection window in case of hospitalization or illness
  - Offer caregiving support
  - Organize transportation services
- Include an older adult advocate on research or advisory team
- Incorporate study measures that matter to older adults
  - Quality of life
  - Function over survival
- Address complexity of older adults in statistical methods

2. Guide for Industry-Sponsored Trials

How to use this tool

This tool provides guidance and ideas on communicating with industry sponsors to ensure the research plan is age-friendly and inclusive.

Guide

Guide for Industry-sponsored Trials

"Enrolling an adequate representation of the range of patients in a clinical trial that may be exposed to a drug after approval can maximize the generalizability of the trial results. It provides the ability to understand the drug's benefit-risk profile across the patient population likely to use the drug in clinical practice (e.g., to identify whether there are differences in the benefits, risks, or both of the drug in different populations). Including information in the labeling describing use in older adults helps to promote the safe and effective use of these products and better informs treatment decisions in clinical practice."

-U.S. Department of Health and Human Services
Food and Drug Administration

- Bring concerns to the sponsor – point out the FDA requirements

- If enrollment is slower than expected, sponsor may consider changing the protocol to be more inclusive

- Request minor changes to recruitment materials to be Age-Friendly – increase font size, update the language, etc.

- Suggest additional recruitment strategies targeted to older adults such as recruiting at local community centers/senior centers. Offer them often and during evening and weekend hours.

- Suggest minor changes to protocol – flexibility with study visits (shorter visits, wider window for follow-up, virtual options), transportation accommodations, consent a caregiver in the event of cognitive impairment

- Suggest an adaptive clinical trial design to allow for pre-specified trial design changes during the trial when data become available – start with a narrow population if there are concerns for safety and expand to a broader population based on interim safety data.

- Suggest modifying or eliminating exclusion criteria from phase 2 studies for phase 3 trials, which have a different objective than phase 2 studies.

For more FDA guidance on enhancing diversity of clinical trial populations, visit https://www.fda.gov/media/127712/download.

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3. Age-Friendly Communication Guide

How to use this tool

This tool helps study teams think about verbal and non-verbal communication with older adult research participants, including suggestions on what to use and avoid in terms of words, behavior and writing style.

Guide

Age-Friendly Communication Guide

AVOID:

Verbal communication

- Stereotyping or reinforcing incorrect perceptions of older adults
- Ageist language, such as "the aged", "the elderly", "oldsters", "senile", etc.
- Patronizing, condescending, or childish expressions and tone
- Formality and professional jargon

Non-verbal communication

- Physical barriers between you and the participant
- Towering over participant; stay seated during conversations
- Doodling or fiddling
- Consulting your watch, phone, or schedule

Written communication

- White text on a dark background
- Use of all italics, all capital letters and underlined type
- Wavy lines or dots
- Crowding text or cramming too much information on a page

USE:

Verbal communication

- "Elders", "older persons", or "older adults" when referring to the age group
- Familiar words and a conversational, personal tone
- Preferred method to address them (Mrs., first name, etc.)
- Most important ideas first
- Action verbs and active voice
- Short words and sentences
- Concrete examples to illustrate ideas or concepts
- Open-ended questions to elicit information

Non-verbal communication

- Good eye contact
- Courteous attention and demonstrate interest
- Demonstrations when asking a participant to do something
- Non-verbal cues to support verbal communication

Written communication

- Bold face type with main ideas and important information
- Checklists or written documents to back up oral instructions
- At least 12-point type
- Dark print on a light background
- A plain, clear typeface for readability
- Matte, non-glossy paper to reduce glare

4. Addressing Common Barriers to Inclusion of Older Adults

How to use this tool

This tool provides information on common barriers to older adult inclusion in research and suggested solutions to address these barriers.

Tool

Addressing Common Barriers to Inclusion

BARRIER	SOLUTIONS
Rigid protocol eligibility criteria • Limited age range • Exclude if comorbidities • Exclude if high-risk medications • Exclude if impaired ability/mobility level • Exclude if impaired Cognition	Ensure exclusion criteria based on scientific necessity only Adapt study procedures and measurement tools to meet participants' needs Use multiple recruitment methods and adapt materials to older adult participants
Time • Length of study • Consent process • Timing and frequency of visits • Time commitment requirements of care/study partner	Build flexibility and adaptability into your study Lengthen study timelines to account for lack of availability (e.g., assess at week 6-8 rather than just week 6) Accommodate study visits to participant's and/or caregiver's schedules Provide breaks for care partner during visits Budget for extra time during study visits
Accessibility of study site • Location and accommodations	Ensure the site is accessible and accommodations are available if needed (e.g. ramps, elevator, wheelchair) Meet participants at their residence Consider telehealth visits
Transportation	Use car services, rideshares or taxis Home visits or telehealth visits
Availability of caregiver study partner	Consent caregiver into study Provide stipend to care partner Engage multiple caregivers

5. Recruitment Recommendations for Older Adults

How to use this tool

This tool provides suggested recruitment methods that research teams can use to connect with, engage and recruit older adults into their research studies.

Tool

Recruitment Methods for Older Adults
Suggested Recruitment Methods
Healthcare system • Use tools within your health records to identify eligible participants • Collaborate with providers and clinics who focus on this age demographic for study referrals • Flyers in clinic space
Disease associations, support, and advocacy groups
Agencies serving those 65+ years old • County departments • Commissions/agencies on aging • Nonprofit organizations • Senior and social services
Housing communities • Independent living or retirement communities • Assisted living • Memory care clinics
Community centers and clubs • Senior centers • Fitness and community centers • Recreation clubs and activity groups
Veteran focused groups (e.g. VFW Halls)
Cultural and faith communities
Social media ad campaigns
Online news & resources • Local senior's resource guide • Retirement connections • "Boomer" news • AARP local chapter newsletter

6. Recruitment Material Checklist

How to use this tool

This tool provides research teams with a list of considerations when developing recruitment materials, to ensure they are inclusive, representative and age-friendly.

Checklist

Recruitment Material Checklist

- o Images – inclusive and representative of the older adult population you are trying to reach
    - o Age of model in image
    - o Race and/or ethnicity of model in image
    - o Relationship status shown, taking into consideration the percentage of older adults who are divorced or widowed
    - o Overall – A potential participant would see themselves reflected in the image(s)

- o Words – materials written in way that can be seen, read and understood
    - o Large font size, viewable for any vision or age level
    - o Words in plain/simple language, understandable to the general public
    - o Use people first language, putting the person before their age
    - o Avoid ageist language (e.g. senile, elderly)
    - o Content that is culturally competent and overall respectful

7. Consent/Information Sheet Knowledge Check

How to use this tool

A knowledge check can be used to ascertain a participant's competency level and identify when a legally authorized representative (LAR) is required for the consent process.

Knowledge Check

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Consent – Information Sheet Knowledge Check

After reviewing the consent form, check the participant's understanding by asking the following questions and determining if their responses are correct or incorrect. Mark the appropriate section and total the number of correct and incorrect responses at the bottom. If 2 or more questions are incorrect, consider having a LAR such as a spouse, adult child, parent, sibling, other relative, or close friend sign the consent form and requiring assent by the participant.

Participant Name/ID: _____   Date: _____

We would like to verify your understanding of what the study is about and of your rights as a study participant. This is a part of our standard procedure.

	Correct	Incorrect
1. **Can you quit the study any time after you have agreed to participate?** Participant is aware that they can discontinue study participation at any time.	_____	_____
2. **What are the main risks of participation in this study?** Participant understands that there are some small risks associated with the study.	_____	_____
3. **What are the potential benefits of participation in this study (other than incentives)?** Participant understands that they will have no direct benefits from the study but that the study will benefit future individuals.	_____	_____
4. **If you do not participate in the study, will it affect your medical care?** Participant understands that declining participation will not affect medical care.	_____	_____
5. **Will the personal information we collect in this study be kept confidential?** Participant understands that all their information will be kept confidential.	_____	_____
Overall capacity to provide informed consent:	_____	_____

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8. Retention Recommendations for Older Adults

How to use this tool

This tool provides suggested retention methods that research teams can use to stay connected with older adult participants over the length of the study, helping to retain them in the study.

Tool

Retention Methods for Older Adults

Suggested Retention Methods
Study newsletter • Provide updates to participants on how the study is going, highlighting the importance and impact of their participation in the study.
Study visit reminders • Call or email participants and/or their caregivers to remind them of upcoming study visits.
Greeting cards • Send participants greeting cards for their birthdays, anniversaries, and other celebratory moments.
Stay connected • Call or email participants and/or caregivers multiple times over the course of the study to stay engaged and check on how they are doing.
Condolence card • Send the caregiver of a participant a condolence card if the participant passes away during the course of the study due to age or disease progression.

Resources for Inclusion of Older Adults

Additional resources to help research teams better understand and include older adults in their research studies:

- National Institute on Aging (NIA): https://www.nia.nih.gov/
- NCATS Inclusion of Older Adults into Clinical and Translational Research Toolkit: https://clic-ctsa.org/education/kits/presentation-materials-library-inclusion-older-adults-clinical-and-translational
- NIA Recruiting Older Adults into Research (ROAR) Toolkit: https://www.nia.nih.gov/health/recruiting-older-adults-research-roar-toolkit
- NIA Alzheimer's & Dementia Outreach, Recruitment & Engagement Resources (ADORE) Toolkit: https://www.nia.nih.gov/research/alzheimers-dementia-outreach-recruitment-engagement-resources
- NIA Communicating with Older Adults for Healthcare Professionals: https://www.nia.nih.gov/health/topics/healthcare-professionals-information
- CDC Healthy Aging Program: https://www.cdc.gov/aging/about/index.htm
- Duke University CTSI - 5Ts Framework: https://guides.mclibrary.duke.edu/ctsisp/5Ts

For more information, additional resources, and to request a recruitment consultation, please visit the OCTRI Recruitment webpage or email us at octrirecruitment@ohsu.edu.

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