



Including Older Adults in Research: Implementing the NIH Lifespan Policy and Recruitment Strategies



Agenda

- 1. Introduction of Speakers
- 2. NIH Lifespan Policy
- 3. Recruitment Experiences and Strategies
- 4. Q&A
- 5. Wrap-up and Announcements



Speakers

• Elizabeth Eckstrom, M.D., M.P.H. General Internal Medicine and Geriatrics

Raina Croff, Ph.D.
Layton Aging & Alzheimer's Disease Center

Allison Lindauer, Ph.D., N.P.
Layton Aging & Alzheimer's Disease Center,
OHSU School of Nursing

Melanie Abrahamson-Sommer, M.P.H.
Department of Endocrinology



NIH Inclusion Across the Lifespan Policy

Elizabeth Eckstrom, M.D., M.P.H. General Internal Medicine and Geriatrics



Why have this conversation?

- Many diseases are common in older people, yet little research has been done in older ages
- Many diseases are distinctly different in older adults, yet haven't been studied in these age groups
- Some older adults enjoy participating in researchbut they tend to be white and advantaged
- Older minority populations have low participation in research
- Clinicians caring for older adults, particularly those from diverse populations, have little evidence to guide their care
- People at the highest risk of disease often have the greatest chance to benefit from research!







The Inclusion Across the Lifespan policy (IAL) applies to *all exempt and non-exempt human subjects research* (see NOT-OD-18-116), beginning with competing grant applications due *on/after January 25, 2019*, and R&D contract solicitations issued on/after this date.

Prior to this date, the <u>Inclusion of Children in Research Policy</u> continues to be in effect.

In applications or proposals:

Include an Inclusion plan

Submit a plan for including individuals across the lifespan

If excluding based on age, provide rationale and justification for the specific age range*

In progress reports:

Report age at enrollment

The policy requires the age of participants at enrollment to be included in reports

Age at enrollment may be reported to NIH in units ranging from hours to years.

Remember: Scientific Review Groups (SRGs) will assess each application/proposal as being "acceptable" or "unacceptable" with regard to the age-appropriate inclusion or exclusion of individuals in the research project.

*Exclusion based on age must be due to ethical or scientific reasons. Acceptable justifications may include:

- The disease to be studied does not occur in the excluded age group
- The research topic is not relevant to the excluded age group
- Knowledge sought is already available for the excluded group
- Separate study for the excluded age group is warranted or preferable
- Research involves data from pre-enrolled participants
- Laws/regulations bar inclusion of individuals in a specific age group in research
- The study poses unacceptable risk to the excluded age group



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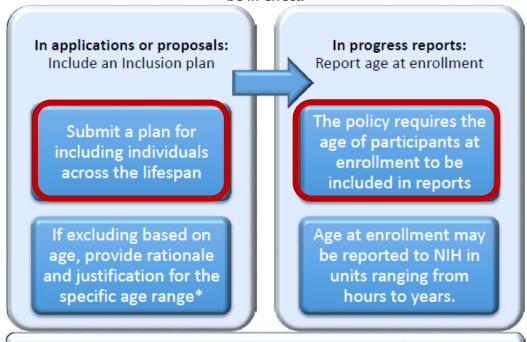
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"Arbitrary upper age limits for trial entry are almost never justified"

FDA



Including Older Adults in Research: Recruitment Experiences and Strategies

Raina Croff, Ph.D. Layton Aging & Alzheimer's Disease Center



SHARP, BRFSS & PreSERVE Coalition Focus groups with Older African Americans

Before, During, After

- Trust-building
- Advisory board
- Community letters of support

Messaging

- Community events Announcements, sign-up sheets, table
- They are the experts
- Diversity in research leads to better research
- Demonstrate community benefit
- Demonstrate the community commitment



SHARP, BRFSS & PreSERVE Coalition Focus groups with Older African Americans

Logistics

- Involve scholars & interns
- Familiar community location
- Phone call reminders
- Day-time meetings
- Relatable moderator
- Build in social time



Including Older Adults in Research: Don't Forget the Tech

Allison Lindauer, Ph.D., N.P. Layton Aging & Alzheimer's Disease Center OHSU School of Nursing



About us...

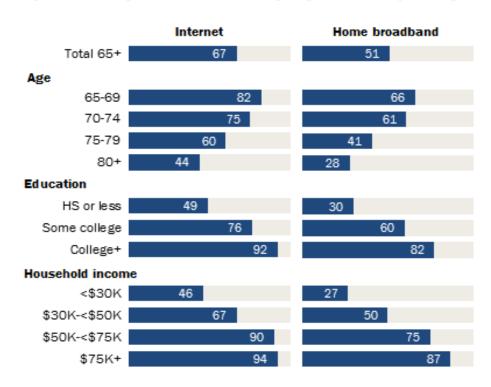
- The Layton Aging & Alzheimer's Disease Center at OHSU is one of 30 NIH Alzheimer's Disease Centers in the United States and the only one of its kind in Oregon.
- The Layton Center conducts studies of promising treatments, technologies for patient support, genetics, neuroimaging and pathology.
- Along with research, we also provide evaluation and treatment for persons with dementia and their family members.



Older Adults and Technology

Internet use and broadband adoption among seniors varies greatly by age, income and education

% of U.S. adults ages 65 and older who say they use/have the following ...



• 67% of adults over 65 use the Internet

 Up to 81% of US adults own smart phones

Source: Survey conducted Sept.29-Nov.6, 2016. "Tech Adoption Climbs Among Older Adults"

PEW RESEARCH CENTER



ACTNOW

- Alzheimer's Comprehensive Treatment Network of Oregon and Washington
- As of December 2018, 339 participants enrolled, 56% completed the survey indicating interest in volunteering for research studies
- 69% age 55 or older
- 52% reported changes in memory



Figure 1: ACTNOW Beta Website Homepage







Tele-STAR

- Support for family members caring for those with dementia
- All caregivers surveyed (n=25) agreed the video-conferencing visits (8 weekly sessions) were easy to attend
- 23 of the 25 (92%) would prefer video-conferencing visits over in-home visits
- All 25 caregivers felt comfortable "discussing sensitive about my family" while on the video-conferencing visits









Including Older Adults in Research: Mr. OS Research Study

Melanie Abrahamson-Sommer, M.P.H. Department of Endocrinology





MrOS Research Study: Study and Recruitment Experience

- Overview of the Study
 - Longevity study with older men who have been enrolled since 2000
 - Same male subjects enrolled for 18 years
- Visits vs. Follow-Up
 - Best practices for not losing contact with participants
- Transportation Concerns
 - How will they get to the study visit?
 - Addressing those needs





MrOS Research Study: Study and Recruitment Experience

- Making the Research Visit a Positive Experience for the Participant
- The Importance of Tracking
 - The who, what, where of the participants' and their lives
- The Consent Process
 - Participant vs. representative/family member consent



Questions & Answers





Wrap Up & Announcements



Announcements

Newest Recruitment Toolkit Documents are Available Online!

- Including Older Adults in Research
 - Best practices and strategies for recruiting older adults into research
- Disease Demographics
 - How-to on determining the demographics for the disease you are researching and next steps

Including Older Adults in Research:

Challenges and Strategies for Recruitment



Disease Demographics:

How to determine the correct patient demographics for the disease you are researching





Upcoming Events

Social Media and Subject Recruitment: How To Make It Work For You

- When: Thursday, February 28th from 1-2pm
- Where: CHH 3070 (4)
- To RSVP, email <u>OHSUCRU@ohsu.edu</u>



Upcoming Events

Clinical Research United Social Hour (CRUSH)

- When: Wednesday, February 27th from 4:30-6:30pm
- Where: Mt. Hood Brewing Co. Tilikum Station
- To RSVP, email OHSUCRU@ohsu.edu

For other upcoming events, stay tuned for announcements in future editions of CRU news.

Don't receive CRU News, email <u>OHSUCRU@ohsu.edu</u> to be added to the listserv.





Thank You

Subject Recruitment Questions? Email octrirecruitment@ohsu.edu

Additional Resources

Inclusion Across the Lifespan Policy https://grants.nih.gov/grants/funding/lifespan/lifespan/policyinfo.htm

"Including Older Adults in Research" – OCTRI Research Forum Presentation https://echo360.org/lesson/4d4321b4-f1fd-49bb-8ed2-442a4ebf0c4b/classroom#sortDirection=desc

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