Clinical Research United
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 research— but 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!
Inclusion Across the Lifespan: guidance for applying the policy

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 Inclusion of Children in Research Policy 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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“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

- 67% of adults over 65 use the Internet
- Up to 81% of US adults own smart phones
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

Oregonians and Washingtonians working together for a cure for Alzheimer's disease
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

NIA P30AG008017; P30AG024978
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
Upcoming Events

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

• When: Thursday, February 28\textsuperscript{th} from 1-2pm
• Where: CHH 3070 (4)
• To RSVP, email OHSUCRU@ohsu.edu
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 OHSUCRU@ohsu.edu 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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