

Barriers to Including Older Adults – the NIH View/Approach

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21st Century Cures Act & Inclusion by Age

- Passed December 2016
- Mandated
 - NIH workshop within 180 days
 - Policy revisit within another 180 days



Baseline NIH Analysis

- NIH-funded Phase III trials from CT.gov thru 2015
- Top 10 causes for hospitalization and/or affected DALYs in older adults
- Analyzed:
 - Mean Age/Age Range
 - Inclusion/Exclusion Criteria
 - Age Requirement

Summary of Key Findings

	Number of studies	Mean age (yrs.)
Congestive Heart Failure	45	61.0±9.2
Cardiac Dysrhythmias	24	58.0±7.5
Coronary Atherosclerosis	106	59.2±6.5
Heart Attack	76	58.8±7.0
Stroke	113	53.3±8.3
COPD	14	58.4±7.1
Pneumonia	48	53.4±7.5
Lung Cancer	117	52.4±6.0
Prostate Cancer	65	65.4±4.6
Osteoarthritis	15	64.6±6.5

Summary of Key Findings in Older Adult Inclusion

- Based on age, participants in trials may not represent real-world populations with the disease
- For diseases highly prevalent among older people, clinical trials often excluded subjects based on age
 - 27% of studies had arbitrary upper age caps
- Indirect exclusion factors may apply
 - Co-morbid conditions (hypertension, diabetes, etc.)
 - Polypharmacy

Common Comorbidities

- 65% of individuals 60 and older have hypertension
- 21.4% of individuals ≥ 65 have diagnosed diabetes mellitus
- Adults 65+ take a median of 4 medications
 - 39% take 5+ medications

Nwanko et al, NCHS data brief, 2013; CDC National Diabetes Statistics Report, 2020; Charlesworth et al, J Gerontol, 2015.

Exclusion Criteria by disease category in Phase 3 studies

		Exclusion Criteria		
Clinical Trial		<u>Poly-pharmacy</u>	<u>Hypertension</u>	<u>Diabetes</u>
	Congestive Heart Failure	29%	12%	12%
	Pneumonia	33%	7%	7%
	Coronary Atherosclerosis	22%	32%	16%
	Cardiac Dysrhythmias	42%	4%	4%
	Heart Attack	12%	14%	33%
	Osteoarthritis	24%	---	---
	Stroke	35%	6%	8%
	COPD	13%	6%	6%
	Lung Cancer	31%	8%	4%
Prostate Cancer	22%	4%	4%	

Percent of clinical trials that exclude participants based on specific exclusion criteria.

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Inclusion Across the Lifespan Workshop

June 1-2, 2017 Bethesda, MD

Purpose: To discuss the challenges and barriers to including children and older adults in clinical research and to identify strategies that would produce more age-inclusive clinical studies.



NIH Inclusion Across the Lifespan Policy Revision

Revision: NIH Policy and Guidelines on the Inclusion of Individuals Across the Lifespan as Participants in Research Involving Human Subjects

Notice Number: NOT-OD-18-116

Key Dates

Release Date: December 19, 2017

Related Announcements

[NOT-OD-16-010](#)

[NOT-98-024](#)

Issued by

National Institutes of Health ([NIH](#))

Purpose

This revised Notice replaces [NOT-98-024](#). The purpose of this Notice is to inform the research community that NIH is revising its NIH Policy and Guidelines on the Inclusion of Children. Changes to the policy include (1) the applicability of the policy to individuals of all ages, including children and older adults; (2) clarification of potentially acceptable reasons for excluding participants based on age; and (3) a requirement to provide data on participant age at enrollment in progress reports.

Inclusion Across the Lifespan: Guidance for Applying the Policy

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,
sex/gender, and race/ethnicity
be included in reports.

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

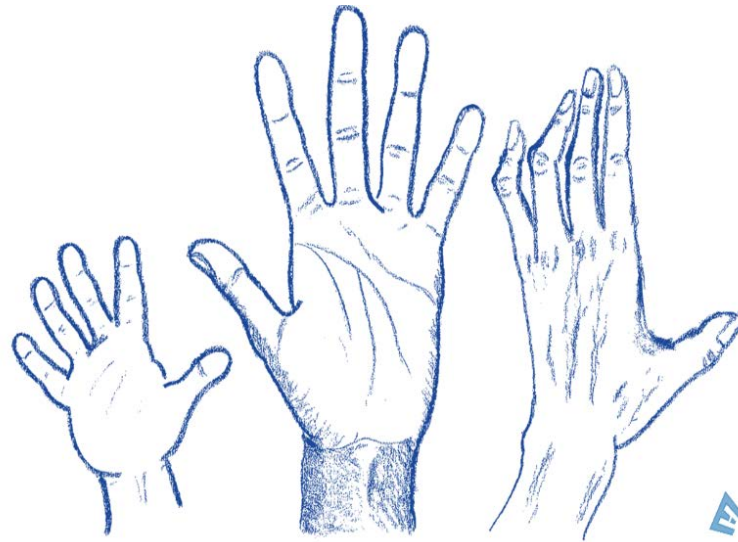
Remember: Scientific Review Groups (SRGs) will assess each application/proposal as being “acceptable” or “unacceptable” with regard to the age-appropriate inclusion or exclusion of individuals in the research project.

Inclusion Across the Lifespan

NIH's 2nd Inclusion Across the Lifespan (IAL-II) Workshop

[NIH Inclusion Across the Lifespan-II workshop website](#)

*The workshop will
be held virtually
and is free of
charge.*



*Registration
open through
September 1st,
2020.*

September 2nd, 2020



*Turning
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Health*