

AGS Report on Engagement Related to the NIH Inclusion Across the Lifespan Policy

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See related Editorial by George Kuchel in this issue.

After passage of the 21st Century Cures Act, the National Institutes of Health held a workshop in 2017 to consider expanding its inclusion policy to encompass individuals of all ages. American Geriatrics Society (AGS) leaders and members participated in the workshop and formal feedback period. AGS advocacy clearly impacted the resulting workshop report and Inclusion Across the Lifespan policy that eliminates upper-age limits for research participation unless risk justified and changes the language used to describe older adults and other vulnerable groups. AGS recommendations that were not specifically stated in the updated

policy were to encourage active recruitment of older adults, add standard measures of function and/or frailty, and change review criteria to ensure the health status of a study population mirrors typical clinical populations. The updated inclusion policy ultimately offers academic geriatrics programs the opportunities to expand knowledge about health in aging and to continue to provide leadership for research and advocacy efforts on behalf of older adults. *J Am Geriatr Soc* 67:211–217, 2019.

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Over the past 3 decades, the National Institutes of Health (NIH) has instituted policies to provide specific guidance regarding research participant inclusion, with the goal of ensuring that NIH-funded research reflects affected populations living with conditions under study. Other federal agencies funding research relevant for the US population have historically adopted NIH inclusion policies. Initially, NIH inclusion policies focused on inclusion of women and minority populations. Then updates were implemented to support inclusion of children.

Most recently, the passage of the 2016 21st Century Cures Act required that the NIH convene a workshop to consider expanding its inclusion policy to include individuals of all ages.¹ In the summer of 2017, American Geriatrics Society (AGS) leaders and members representing a range of aging-research expertise participated in an NIH workshop focused on an updated Inclusion Across the Lifespan policy.² Workshop presentations highlighted that older people and children are often excluded from clinical research studies, sometimes without a strong scientific or ethical rationale.^{3,4} AGS participation in the workshop and

formal feedback following a request for information clearly influenced the resulting Inclusion Across the Lifespan policy and workshop report, both published on December 3, 2017.⁵

In this article, we provide details about AGS engagement in the process that led to this policy change and to the integration of the recommendations for reframing aging into the conference report and broader next steps.⁶ We also propose strategies that AGS members and academic geriatrics programs should consider to support better representation of older adults in clinical research and to integrate geriatrics expertise into future clinical trials. A companion article included in this issue presents new data from program staff at the National Institute on Aging (part of the NIH) that further highlights gaps in representing older adults in NIH-funded clinical research related to conditions that disproportionately affect us all as we age.⁷

SUMMARY OF THE INCLUSION ACROSS THE LIFESPAN POLICY

The new Inclusion Across the Lifespan policy that impacts all NIH proposals or competing renewals with due dates starting January 25, 2019, will eliminate arbitrary age limits. Previous guidance required justification for the inclusion or exclusion of children. Investigators will now be asked to provide a scientific justification for excluding older adults on the basis of age.

The new policy also includes potentially acceptable reasons to exclude certain age groups. For instance, it is appropriate to exclude people in age groups in whom a disease does not occur or for whom knowledge regarding the scientific question is already available. Understandably, if the study will collect or analyze data on pre-enrolled study participants, such as those in an existing cohort study, then participants from across the lifespan will not be available. In some cases, an age-specific study in a previously excluded age group is warranted and preferable.

Adherence to the new policy will be assessed during scientific review, with review panels determining whether inclusion/exclusion criteria because of age are “acceptable” or “unacceptable.” Assessment of whether the proposed age range is reasonable for the scientific goals of the study may also factor into the priority score given an application. If reviewers determine that an application has unacceptable inclusion/exclusion criteria, the policy states that the study will not be funded until this issue is resolved.

SUMMARY OF NIH IMPLEMENTATION OF THE POLICY CHANGE

Federal law required consideration of policy changes related to Inclusion across the Lifespan within 180 days of the workshop, resulting in rapid adoption by the NIH. Staff training has been completed with all review officers and program officers. NIH is providing training for investigators regarding the inclusion policy as part of its general outreach during NIH regional seminars, professional society meetings, and other standard NIH training. In addition, NIH leaders are preparing a summary article outlining the history of NIH inclusion policies and expectations for this new policy.

To facilitate monitoring inclusion enrollment for human subject research, the NIH changed its Inclusion Management System to a new Human Subjects System (HSS). HSS allows the submission of anonymized individual-level data on subjects in ongoing studies. Such submissions will become mandatory in progress reports for projects submitted and funded starting January 25, 2019. Pertinent information regarding the HSS can be accessed at https://era.nih.gov/hss_overview.cfm and https://era.nih.gov/hss_training.htm.

Briefly, grant recipients can view/edit/update existing enrollment data, create new enrollment reports, and make off-cycle corrections or updates using this system, entered through the online interface eRACommons. In the future, researchers will be able to use data from the HSS to initiate and populate a ClinicalTrials.gov registration. Users will be required to upload participant-level data using a standardized report form, so age-specific inclusion can be monitored more easily.

Investigators are reminded to include language during the informed consent to transmit deidentified individual data on sex/gender, race, ethnicity, and age at enrollment to NIH (given limited numbers, those people 90 years of age or older will be reported in aggregate to protect confidentiality). Program officers will conduct inclusion enrollment reviews at least yearly at the time of progress report, and they can request more frequent reviews if concerns are noted. Training for investigators is available on accessing and using the new reporting system.

Because the new policy encompasses all of NIH, there are no planned changes to inclusion language in specific Funding Opportunity Announcements (FOAs). However, there are upcoming changes to review criteria in FOAs related to the policy (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-228.html>). Language in the reviewer package was changed to define “older adults” using AGS-advocated terminology. An FOA for applications related to the science of recruitment across the lifespan was open at the time of this article’s publication.⁸ It is not yet clear how the policy will be viewed and enforced by reviewers in actual practice; this remains an area the NIH will monitor closely.

AGS ADVOCACY RELATED TO NIH INCLUSION ACROSS THE LIFESPAN POLICY AND WORKSHOP REPORT

During the workshop and in formal comments following the workshop, AGS advocated for these changes:

- *Eliminating upper-age limits for participants unless risk justified.* Exclusion of trial participants based on arbitrary upper-age restrictions complicates further research and clinical practice in several key ways. Upper-age limit exclusions lead to studies that fail to analyze outcomes for some of the people most likely to experience a disease or condition. Thus these studies result in evidence not applicable to the population living with a condition. AGS representatives advocated that exclusion criteria should only limit involvement of older adults with a significant health risk associated with participation. Guidance from the final Inclusion Across the Lifespan policy focuses on developing realistic inclusion/exclusion criteria so that participants with comorbidities or physical/cognitive limitations

common in the study population still can be represented in research and its findings.

- *Changing the language used to describe older adults and other vulnerable groups.* One goal of the workshop was to engage scientific journals in discussion given their important role in disseminating results. Both during the workshop and in formal comments to NIH following the workshop, the AGS highlighted the recent work emanating from the Reframing Aging Initiative undertaken by the Leaders of Aging Organizations (LAO), of which the AGS is a member. The AGS also highlighted related changes made by the *Journal of the American Geriatrics Society (JAGS)* to its editorial policies.⁶ The Inclusion Across the Lifespan workshop summary made specific reference to the AGS position that describing individuals older than 65 years with terms such as “the elderly” could reinforce alienation, whereas terms like “older adults” were more likely to accomplish the important aim of building “increased respect and understanding.”³

The companion piece in this issue by Lockett et al highlights the impact of arbitrary age limits and condition-specific exclusions in previous NIH-funded phase III clinical trials to limit the available evidence base for the 10 most common conditions impacting hospitalization or disability among older adults. The analysis further reveals gaps in the current evidence base and opportunities for aging researchers to apply the new policy and develop more generalizable studies on behalf of older vulnerable populations. Further, the article illustrates the difficulty in identifying published studies that were inclusive of older populations because of inconsistent definitions for the older adult study population in terms of both language and methods for reporting age.

WORKSHOP RECOMMENDATIONS NOT CURRENTLY ADDRESSED BY THE POLICY

It is notable that some recommendations from the workshop endorsed by the AGS were not addressed in the policy due to concerns from various stakeholder groups. Several key points were implied but not specifically stated in the policy. For example, workshop attendees stressed that older adults should not simply be included in a token way, but that inclusion must be meaningful. In some instances, trials should solely focus on older adults (eg, statins for primary prevention).⁹ Enrollment plans should use evidence-based strategies for recruitment and retention of older populations when applicable, so the health status of the study population mirrors that of persons living with the condition under study.^{10,11} Currently, the NIH will rely on reviewers and scientific review officers to evaluate and promote these important aspects of inclusion of older adults in new applications.

Workshop attendees further stressed to NIH that the peer review research process needs to ensure appropriate aging-research expertise on review panels assessing research designs and enrollment/retention plans for older adults. Finally, because the health and function of older adult populations remains heterogeneous at any given chronological age, workshop participants encouraged the NIH to consider additional measures of health status such as gait speed, self-reported

health, comorbidity burden, or frailty indices. This is critical for readers to understand whether the health status of the study population mirrors the typical clinical population. The NIH is conducting discussions with various groups interested in functional outcomes, for example, with the National Advisory Board on Medical Rehabilitation Research. However, no standard functional measures have yet been adopted. Therefore, researchers will be able to continue including participants who are healthier, relatively speaking, than the target population despite including more older adults in clinical research.

In addition, the importance of reporting age-related population characteristics consistently in journal articles was considered. Consistency in reporting such information could facilitate summarizing the findings of multiple studies assessing important clinical questions and also help clinicians assess the relevance of study findings to the populations of patients for whom they provide care. However, concerns were raised about the challenges of achieving consensus regarding this issue among journal editors. AGS’s success (described later) influencing publication guidelines to use preferred terms when reporting research findings relevant to older adults may provide a foundation for additional efforts to impact reporting standards across the peer-reviewed literature.

FUTURE DIRECTIONS AND OPPORTUNITIES FOR ACADEMIC GERIATRICS

At the time of the workshop, *JAGS* had just published an editorial outlining changes to its author guidelines regarding the language about aging.⁶ The editorial stemmed from AGS engagement in the Reframing Aging Initiative, undertaken by the LAO. With funding support from a number of private foundations (AARP, Archstone Foundation, the Atlantic Philanthropies, Endowment for Health, Fan Fox and Leslie R. Samuels Foundation, the John A. Hartford Foundation, the Retirement Research Foundation, Rose Community Foundation, and the SCAN Foundation), the LAO engaged the FrameWorks Institute to gain a better understanding of how the language we currently use when describing older people has been heard by the public, media, and policymakers, and to develop recommendations for how advocates could change that language to support better public understanding of our work.¹²

With the *JAGS* editorial team, AGS had identified refining the language used when reporting the results of aging research as an important avenue for implementing the FrameWorks recommendations. As a result, *JAGS* identified preferred terms (“older adult” or “older people,” specifically) and instituted requirements for reporting age specificity when describing study participants in research findings in early 2017. These changes to editorial guidelines led by AGS were well aligned with the workshop goal of engaging scientific journals to “consider opportunities for enhanced participation of these populations regardless of whether the research was funded by the NIH,”⁴ and the recommendations were subsequently included in the workshop report.³

In addition to shaping discussions on changes to how research is conducted (described earlier), formal recognition of more inclusive terminology in the workshop report also offered an important “rising tide to lift all ships” in how research findings can be *reported* more dynamically. ClinicalTrials.gov, for example, has adjusted one of its age categories from “Seniors:

Table 1. Proposed Revisions to *AMA Manual of Style*

Current manual	AGS suggestion
Section 2: Style Chapter 11: Correct & Preferred Language 11.5—Age and Sex Referents	
Use specific terminology to refer to persons' age. See also 11.10.3, Inclusive Language, Age.	Use specific terminology to refer to persons' age. Whenever possible, include information about the age range, average age, and median age of the study population. See also 11.10.3, Inclusive Language, Age.
[. . .] Adults are persons aged 18 years and older and should be referred to as men or women. Persons 18 to 24 years of age may also be referred to as young adults.	[. . .] Age specificity (including age range, average age, and median age, if possible) is generally preferred on first reference to a study population. On second reference, or when referring to groups generally, adults are persons aged 18 years and older and should be referred to as men or women. Persons 18 to 24 years of age may also be referred to as young adults. Persons 65 years and older may also be referred to as older people or older adults.
Section 2: Style Chapter 11: Correct & Preferred Language 11.10.3—Age	
Discrimination based on age (young or old) is ageism. Because the term elderly connotes a stereotype, avoid using it as a noun. When referring to the entire population of elderly persons, use of the elderly may be appropriate (as in the impact of prescription drug costs on the elderly, for example). Otherwise, terms such as older persons, older people, elderly patients, geriatric patients, older adults, older patients, aging adults, persons 65 years and older, or the older population are preferred.	Discrimination based on age (young or old) is ageism. Because terms like seniors, elderly, the aged, aging dependents, old-old, young-old, and similar “other-ing” terms connote a stereotype, avoid using them. Terms such as older persons, older people, older adults, older patients, older individuals, persons 65 years and older, or the older population are preferred.
Note: In studies that involve human beings, age should always be given specifically. Researchers in geriatrics may use defined terms for older age groups, eg, young-old (usually defined as 60 or 65 to 70 or so years) and old-old (80 years and older). See also 11.5, Age and Sex Referents.	Note: In studies that involve human beings, age should always be given specifically (eg, “older people aged 75 to 84,” “older adults over age 65”). See also 11.5, Age and Sex Referents.
Adultism is a form of ageism in which children and adolescents are discounted.	Adultism is a form of ageism in which children and adolescents are discounted.

66+” to “Older Adults: 65+.” Because all NIH-funded clinical trials must be registered on Clinicaltrials.gov, there is potential for behavioral modification simply based on investigators aligning with the verbiage used by the database. The AGS also has successfully advocated for changes to terminology and descriptors relevant to older people in the *American Medical Association Manual of Style* (Table 1) and has made similar requests to editorial boards responsible for the *American Psychological Association Publication Manual* (Table 2) and the *Associated Press Stylebook* (Table 3). These critical resources set a baseline standard for how we report research findings, both in peer-reviewed journals and related news coverage. Effecting change *here* will be key to ensuring that the language we use when we talk about aging research helps policymakers and the public understand the importance of research to improving how we all age.

POLICY CHANGES IN OTHER FEDERAL AGENCIES AND INDUSTRY

Workshop attendees recommended that the NIH Inclusion Across the Lifespan policy be adopted by all federal agencies. The Food and Drug Administration (FDA) convened a public meeting held April 16, 2018, “Evaluating Inclusion

and Exclusion Criteria in Clinical Trials.” Dr. Marie Bernard, deputy director of the National Institute on Aging, presented highlights from the June 2017 NIH workshop. AGS was represented on the “Inclusion of Older Adults and Patients with Multiple Chronic Conditions” panel that addressed these questions: What are the considerations for excluding elderly patients and patients with concomitant illness? What are barriers to enrollment when there are not specific exclusions? and What strategies can be used to enhance inclusion and increase enrollment?

Materials from this public meeting are available at <https://healthpolicy.duke.edu/events/evaluating-inclusion-and-exclusion-criteria-clinical-trials>. No other agency changes are known to be undertaking a similar approach at this time. This work builds on previous engagement of AGS leaders with the FDA.¹³ Substantial changes in pharmaceutical-industry practice will likely require revised FDA policies, but several large companies are developing new internal guidance and training materials to enhance inclusion of older adults.

OPPORTUNITIES FOR ACADEMIC GERIATRICS

The AGS believes the NIH Inclusion Across the Lifespan policy represents an opportunity for academic geriatrics in

Table 2. Proposed Revisions to *American Psychological Association Publication Manual*

Current copy	AGS suggestion
Chapter 3: Writing Clearly & Concisely	
General Guidelines for Reducing Bias	
Guideline 1: Describe at the Appropriate Level of Specificity	
[. . .] To describe age groups, give a specific age range (“ages 65-83 years”) instead of a broad category (“over age 65”). [. . .]	To describe age groups, give a specific age range (“ages 65-83 years”) instead of a broad category (“over age 65”). Additional information on age specificity (including average age and median age) should also be included whenever available.
Chapter 3: Writing Clearly & Concisely	
General Guidelines for Reducing Bias	
Guideline 2: Be Sensitive to Labels	
Respect people’s preferences; call people what they prefer to be called. Accept that preferences change with time and that individuals within groups often disagree about the designations they prefer. Make an effort to determine what is appropriate for your situation; you may need to ask your participants which designations they prefer, particularly when preferred designations are being debated within groups. Avoid labeling people when possible. A common occurrence in scientific writing is that participants in a study tend to lose their individuality; they are broadly categorized as objects (noun forms such as <i>the gays</i> and <i>the elderly</i>) or, particularly in descriptions of people with disabilities, are equated with their conditions— <i>the amnesiacs</i> , <i>the depressives</i> , <i>the schizophrenics</i> , <i>the LDs</i> , for example. One solution is to use adjectival forms (eg, “ <i>gay men</i> ,” “ <i>older adults</i> ,” “ <i>amnesic patients</i> ”). Another is to “put the person first,” followed by a descriptive phrase (eg, “people diagnosed with schizophrenia”). Note that the latter solution is preferred when describing people with disabilities. [. . .]	Avoid labeling people. A common occurrence in scientific writing is that participants in a study tend to lose their individuality; they are broadly categorized as objects (noun forms such as <i>the gays</i> and <i>the elderly</i>) or, particularly in descriptions of people with disabilities, are equated with their conditions— <i>the amnesiacs</i> , <i>the depressives</i> , <i>the schizophrenics</i> , <i>the LDs</i> , for example. On first reference to a group of older people, be as specific as possible by including age range, average age, and median age, where available. Because terms like seniors, elderly, the aged, aging dependents, old-old, young-old, and similar “other-ing” terms connote a stereotype, avoid using them. Terms such as older persons, older people, older adults, older patients, older individuals, persons 65 years and older, or the older population are preferred. Additionally—particularly when describing people with disabilities or those who live with specific health conditions, practice “putting the person first,” followed by a descriptive phrase (eg, “older people diagnosed with schizophrenia”).
Chapter 3: Writing Clearly & Concisely	
Reducing Bias by Topic	
3.16: Age	
Age should be reported as part of the description of participants in the Method section. Be specific in providing age ranges; avoid open-ended definitions such as “under 18 years” or “over 65 years.” [. . .] The terms <i>elderly</i> and <i>senior</i> are not acceptable as nouns; <i>boomer</i> or <i>baby boomer</i> should not be used unless they are related to a study on this topic. The term <i>older adult</i> is preferred. Age groups may also be described with adjectives. Gerontologists may prefer to use combination terms for older age groups (<i>young-old</i> , <i>old-old</i> , <i>very old</i> , <i>oldest old</i> , and <i>centenarians</i>); provide the specific ages of these groups and use them only as adjectives.	Age (including age range, average age, and median age) should be reported as part of the description of participants in the Methods section. Be specific in providing age ranges; avoid open-ended definitions such as “over 65 years.” [. . .] Because terms like seniors, elderly, the aged, aging dependents, old-old, young-old, very old, oldest old, and similar “other-ing” terms connote a stereotype, avoid using them. Terms such as older persons, older people, older adults, older patients, older individuals, persons 65 years and older, or the older population are preferred.

several domains consistent with the Future of Geriatric Medicine Task Force Recommendations.¹⁴

1. *Expansion of knowledge related to health in aging.* The mandate for investigators to upload individual-level age data provides new opportunities for preplanned and post hoc meta-analysis to examine age by treatment interactions in clinical trials or important subgroup differences in observational studies. These may be fruitful areas where early investigators can obtain preliminary data or identify new focal points.
2. *Education across disciplines.* To implement this new policy effectively in studies of age-related conditions across healthcare, investigators, statisticians, and study staff outside gerontology/geriatrics will need additional training and support from researchers with relevant expertise.

Table 4 suggests areas for geriatrics and gerontology researchers to develop educational materials and toolkits for dissemination across their institutions. Aging centers could create a core service to review clinical studies before submission to optimize inclusion plans.

3. *Advocacy for older adults.* The Inclusion Across the Lifespan workshop emphasized the need for a paradigm shift from “protecting vulnerable subjects *from* research” to “protecting vulnerable subjects *through* research.” It is important that institutional review board members, researchers, and potential research subjects understand that underrepresenting older adults and those with multimorbidity in clinical research results in potentially unsafe and inappropriate care decisions. The release of the NIH policy provides an opportunity for geriatrics researchers to advocate directly to these groups.

Table 3. Proposed Revisions to *Associated Press Stylebook*

Current copy	AGS suggestion
Ages	
Use when deemed relevant to the situation. If someone is quoted as saying, <i>I'm too old to get another job</i> , the age is relevant. Generally, use ages for profiles, obituaries, significant career milestones, and achievements unusual for the age. Use ages for people commenting or providing information only if their age is relevant to their comments (eg, a teenager's comment on video games aimed at that age group). Appropriate background, such as <i>a parent of two young children</i> or <i>a World War II veteran</i> , may suffice instead of actual age.	Use when deemed relevant to the situation. If someone is quoted as saying, <i>I'm too old to get another job</i> , the age is relevant. Generally, use ages for profiles, obituaries, significant career milestones, and achievements unusual for the age. Use ages for people commenting or providing information only if their age is relevant to their comments (eg, a teenager's comment on video games aimed at that age group, a health recommendation based on a study of women in their 80s). Appropriate background, such as <i>a parent of two young children</i> or <i>a World War II veteran</i> , may suffice instead of actual age.
Always use figures. <i>The girl is 15 years old; the law is 8 years old; the 101-year-old house</i> . When the context does not require <i>years</i> or <i>years old</i> , the figure is presumed to be <i>years</i> .	Always use figures. <i>The girl is 15 years old; the law is 8 years old; the 101-year-old house</i> . When the context does not require <i>years</i> or <i>years old</i> , the figure is presumed to be <i>years</i> .
Use hyphens for ages expressed as adjectives before a noun or as substitutes for a noun.	Use hyphens for ages expressed as adjectives before a noun or as substitutes for a noun.
Examples: <i>A 5-year-old boy</i> , but <i>the boy is 5 years old</i> . <i>The boy, 7, has a sister, 10</i> . <i>The woman, 26, has a daughter 2 months old</i> . <i>The race is for 3-year-olds</i> . <i>The woman is in her 30s</i> (no apostrophe).	Examples: <i>A 5-year-old boy</i> , but <i>the boy is 5 years old</i> . <i>The boy, 7, has a sister, 10</i> . <i>The woman, 26, has a daughter 2 months old</i> . <i>The race is for 3-year-olds</i> . <i>The woman is in her 30s</i> (no apostrophe).
See also boy, girl, infant, youth, numerals, and elderly .	See also boy, girl, infant, youth, numerals, and older adult .
Elderly	
Use this word carefully and sparingly. Do not refer to a person as <i>elderly</i> unless it is clearly relevant to the story. Apply the same principle to terms such as <i>senior citizen</i> .	An outdated term for older individuals. Use <i>older adult(s)</i> or <i>older person/people</i> instead.
It is appropriate in generic phrases that do not refer to specific individuals: <i>concern for the elderly</i> , <i>a home for the elderly</i> , etc. If the intent is to show that an individual's faculties have deteriorated, cite a graphic example and give attribution for it. Use age when available and appropriate.	If the intent is to show that an individual's faculties have deteriorated, cite a graphic example and give attribution for it. Use age when available and appropriate, especially when reporting on research or recommendations for a specific subset of the population. Example: <i>The researchers found that weekly exercise decreased the risk of diabetes among older adults in their 70s and 80s</i> . See older adult .
Older Adult [Proposed Addition]	
N/A	The preferred term for a person or people 65 years old or older.
Senior Citizen	
Use the term sparingly. See elderly .	An outdated term for older people. Use <i>older adult(s)</i> or <i>older person/people</i> instead. See older adult .

Table 4. Educational Needs of Investigators and Study Staff on Inclusion Plans that can be Addressed by Geriatrics Researchers

Topic	Learning objectives
Evidence-based practices for participant recruitment, consent/assent	<ol style="list-style-type: none"> 1. Use of purposeful recruitment, and working with stakeholders to understand potential barriers to recruitment and retention 2. Use of proactive recruitment strategies including engaging the communities 3. Assessing capacity to provide informed consent, inclusion of legally authorized representatives
Study design	<ol style="list-style-type: none"> 1. Strategies to remove logistical barriers (transportation, mobility, sensory impairment) 2. Minimize acceptable criteria to balance scientific justification vs generalizability 3. Use of alternative study designs to allow for greater inclusion: adaptive trials (ie, sequential, multiple assignment, randomized trials); platform trials (flexible features, such as dropping treatments for futility, declaring one or more treatments superior, or adding new treatments to be tested during the course of a trial); preference designs; pragmatic trials
Data collection, analysis, and reporting	<ol style="list-style-type: none"> 1. Multivariable risk-based analytic methods needed to address heterogeneity 2. Choosing analytic strategies to maximize the potential knowledge gained from preplanned subgroups or stratified recruitment

4. *Leadership.* As institutions develop infrastructure and resources to respond to the new NIH policy, geriatrics researchers should advocate for leadership roles in such initiatives. This may include roles in institutional review boards, clinical translational science centers, or clinical research units. Geriatrics researchers should lead the charge not only in adopting more inclusive terminology and in reporting research findings, but also in advocating for systemic changes at the journal or manuscript-style standards level.

CONCLUSION

There is a vital need to include people of all ages in clinical trials for clinical and research reasons, especially older adults. The new NIH policy on Inclusion Across the Lifespan, informed by AGS advocacy, is an exciting advance in the right direction. The policy for more representative inclusion is especially important for those in older ages, given the increasing prevalence of many diseases among the growing population of those older than 65 years. The new policy helps in two specific ways: (1) to eliminate upper-age limits whenever possible for enrollment (without risk justification), and (2) to change the language used to be more aligned with the Reframing Aging Initiative of AGS when describing older adults.

From a clinical perspective, to have evidence that applies to those who are most likely to live with chronic conditions, we must do better to enroll older adults in a meaningful way. From a research perspective, given that some diseases are far more likely to occur in older adults, including cancer and cardiovascular disease, we must make extra efforts to design studies that will specifically enroll those patients.

AGS advocates that other policy improvements, not yet formally adopted, should also be pursued including the active recruitment of older adults, the inclusion of measures of function and/or frailty, and the use of specific review criteria to avoid tokenism by continuing the practice of including primarily healthier older adults who do not represent the typical older patient. In the meantime, these additional policies must be pursued through review policies and practices during grant reviews. Finally, this gap between the adopted policy and the recommendations not adopted by NIH represent an advocacy opportunity for academic geriatricians from AGS to pursue in the coming months and years.

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