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Leading Change. Improving Care for Older Adults.

AGS Section

New NIH Research Policy Seeks Greater “Inclusion Across Lifespan”; AGS Editorial Explains How. . . And Why

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The pipeline of research supporting care as we age is about to look a bit more like the country it serves—and for good reason. Beginning this year, the National Institutes of Health (NIH) began requiring that NIH-funded scholars eliminate arbitrary age limits in their work, age limits that previously allowed for excluding groups like older people without just cause. A series of articles recently published in the *Journal of the American Geriatrics Society (JAGS)* explores how the change came to fruition—in large part thanks to advocacy from organizations like our own American Geriatrics Society (AGS).¹

Clinical research, much of it championed by NIH scientists, has made increased longevity a true reality. But as the authors of our *JAGS* editorial note, we need greater attention to age in current and future scholarship to keep up that momentum. We all have unique physiological changes and medical care needs as we get older, and the insights researchers gain working with older people today will teach us how to be healthier tomorrow.

Effective as of Jan. 25, the new NIH “Inclusion Across the Lifespan” policy supports research involving traditionally underrepresented age groups—specifically older people and children—by requiring approved justifications before any study participants can be excluded from NIH-funded work based on age alone.¹ The policy also advocates for sensitivity in the language used to describe older adults, stressing the importance of building “respect and understanding” beginning with how we describe older participants in clinical research.¹

In an editorial authored by AGS representatives and published in *JAGS*, geriatrics experts describe how influential stakeholders like the AGS worked closely with the NIH to ensure older adults would have more of a presence in future government-funded health scholarship.¹

“In workshops and comments submitted to NIH, we stressed that excluding trial participants based on arbitrary age restrictions complicates research and jeopardizes findings that could help those most likely to experience a disease or condition,” noted Cathleen Colon-Emeric, MD, MHS, co-author of the editorial.² “We believe this new policy represents an opportunity for geriatrics researchers to develop better care for all our needs as we age.”²

To support these mandates, the AGS authors advocate leading the charge by:

- **Making use of new and better data about older people to conduct deeper and more extensive analyses of treatments and interventions.**¹
- **Helping colleagues across health care understand how to engage older adults in aging research.**¹ A related editorial in *JAGS*, for example, describes a framework for supporting the inclusion of older adults in research by helping scientists pivot to specific priorities for recruiting older participants.³
- **Advocating for older adults.** The Inclusion Across the Lifespan policy advocates a paradigm shift from protecting vulnerable individuals “from research” to protecting them “through research.”¹ AGS authors emphasized the importance of doing so by acknowledging that underrepresenting older adults and other groups in research studies can result in “unsafe and inappropriate care decisions” based on incomplete data.¹
- **Developing infrastructure and resources for review boards, research centers, and even individual researchers to adopt more inclusive practices—and more inclusive terminology—for older adults.**¹

The new policy comes at a critical juncture. Even as older adults become one of the U.S.’s largest age groups, research still lags behind shifting demographics. A study conducted by colleagues from the National Institute of Aging (a division of the NIH), for example, examined the adequacy of age inclusivity in NIH-funded Phase III clinical trials.⁴ Looking at work published from 1965 to 2015, the team determined that more than 33% of studies had upper-age limits, and that 25% of these studies specifically excluded people 65-years-old and older.⁴ Findings are even more stark for certain conditions common with age: More than 70% of trials for cardiac dysrhythmias, coronary atherosclerosis, heart attack, COPD, and lung cancer excluded people over age 75.⁴ The most commonly excluded “condition” overall though: polypharmacy or concomitant medication.

As AGS members and geriatrics researchers know, advances in health extend well beyond merely discovering new treatments;

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they also involve uncovering how those treatments affect the complex care of unique individuals like older adults and how the treatments can improve health, safety, and independence for older adults. The NIH is taking an important step toward ensuring research reflects reality. Groups like the AGS and our members are excited to be among the first to chart that new frontier—and for those of you interested in learning how to get started, we are here to help! Several sessions at the AGS Annual Scientific Meeting addressed opportunities for supporting better inclusion of older adults in health research. To access highlights and slide sets for free, visit GeriatricsCareOnline.org.

References

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