David Kosub: Hello, and welcome to another edition of NIH's All About Grants podcast. I'm your host, David Kosub, with the NIH's Office of Extramural Research. So, to ensure that the knowledge that we acquire from NIH-supported research is applicable to those affected by the condition under study, as well as that that knowledge can be applied to make better-informed medical decisions, we must include a variety of participants in our supported research. This includes considering things such as sex, gender, race, ethnicity, and also the age of the participants. And that's what brings us here today. We have with us Ms. Dawn Corbet, who is NIH's inclusion policy officer, to talk about the NIH inclusion across the lifespan policy, and how it affects how applicants and awardees design their studies. Thank you for being with us. So, let's jump right in, Dawn. Can you briefly give us some context as to the history of this policy, and how it relates to the decades-old policy that many of our listeners may be familiar?

Dawn Corbet: Sure, David. For the last two decades, it has been the policy of NIH that children must be included in all research involving human subjects, unless there are scientific or ethical reasons not to do so. In December 2016, the 21st Century Cures Act was passed, and this act included a number of provisions affecting research with participants. In particular, it required NIH to hold a workshop on age grouping and exclusions, but also that we publish guidelines addressing consideration of age in clinical research and publish the number of children in NIH research. Fortunately, NIH had been thinking about this issue for a while, and we had already planned to have a workshop on looking at the age of participants in our research. And so, in June 2017, we held a workshop with over 200 participants, including researchers, clinicians, patient advocates and others to discuss barrier and facilitators to the inclusion of volunteers of all ages in our clinical research studies. We also issued a request for information to get feedback from the broader scientific community on this issue, and among the themes that we heard were first that children and older adults are often excluded from clinical research studies, and in some cases, without a clear scientific or ethical rationale for their exclusion. And two, that data about the age of participants in clinical research studies is not readily available, which limits the ability of clinicians, researchers, and others to understand how the results may be generalized to certain age groups, such as children and older adults. And so, in December of 2017, NIH revised its inclusion of children policy to include individuals of all ages, and we now call it the Inclusion Across the Lifespan policy.

David Kosub: Great. And it's important for our listeners to be aware that this policy will be effective for applications submitted to NIH seeking support that involve human participants in the research on January 25th, 2019. So, Dawn, when our applicants are putting together their applications, what should they be thinking about to make sure that they comply with this policy?

Dawn Corbet: Well, applicants are currently asked to justify the proposed age range of study participants and the inclusion of children in the section in their application. And they should continue to do so. They should explain why the proposed age range is appropriate in the context of the scientific question proposed and provide a scientific or ethical rationale for the exclusion of any age groups. So, for example, if you were recruiting individuals 18 to 65, you should explain why that age range is appropriate in the context of the science, and specifically explain why children and older adults over the age of 65 are excluded from that study. When preparing an application, it's also important for applicants to consider the age range of their participants in plans for recruitment and retention. So, considering factors such as how individuals may get to the study site, how waiting times can be minimized, how much time the study team needs to explain the study and interact with potential participants can help investigators ensure participants of all ages are able to participate in their study.

David Kosub: You mentioned some exclusions. Can you talk more about when a participant may be excluded from clinical research as part of this policy?

Dawn Corbet: Sure. NIH does not expect that individuals of all ages are going to be included in every study, and in some cases it's not scientifically or ethically appropriate to include participants of various ages. So, for example, NIH may not expect children to be included in a study on Alzheimer's disease, and we may not expect to see older adults in a study focused on managing Type 1 diabetes in adolescents. When a condition doesn't occur in a particular age group, or when a separate age-specific study is warranted, NIH does not expect to see inclusion of all age groups. There are also some additional circumstances in which exclusion of individuals based on age may not be appropriate, such as when it would not be ethical to include individuals in the study. NIH's guide notice announcing the Inclusion Across the Lifespan policy explains additional circumstances in which excluding individuals based on age may be appropriate.

David Kosub: Okay, great. Let's jump to the review process now. What might a study section be thinking about regarding this policy as they review an application’s scientific merit?

Dawn Corbet: Reviewers are going to look at your application to determine if the age range and participants that you propose is justified in terms of the scientific goals and the research strategy proposed. And they will factor their assessment into the priority score of the application. Reviewers may determine that inclusion based on age is unacceptable, in which case the study will not be funded until this is resolved.

David Kosub: Now, again, as a reminder, this policy is effective on January 25th, 2019. So, if someone gets an award after that time point, what should they be thinking about when it comes to reporting and compliance as part of this policy?

Dawn Corbet: So, applications submitted on or after January 25th, 2019 are expected to submit de-identified individual level participant data on sex, gender, race, and ethnicity, and age at enrollment. So, if you've received an NIH grant in the past, you may be familiar with the aggregate tables on which you report participant sex or gender, race and ethnicity. NIH refers to these tables that are submitted with annual progress reports as inclusion enrollment reports. Investigators will instead submit a spreadsheet with these data at an individual level. In other words, you'll have one row of data for every participant, with the sex or gender, race, ethnicity, and age at enrollment of the participant. Investigators should consider how they will collect information on these variables when they're designing their study in order to report this information in their annual progress reports. We expect that reporting data at the individual participant level will be easier for investigators, as it eliminates the step of aggregating the data into those tables. So, now you can just send us a spreadsheet with your data, and our systems will do the aggregating for you.

David Kosub: Pretty cool. Any final thoughts you would like to leave with our listeners?

Dawn Corbet: Just that NIH looks forward to having more age-inclusive studies and having available more information about the ages of participants in our research to help us ensure the knowledge gained from the research we support is applicable to all those affected by the condition under study.

David Kosub: Great, great, great. Appreciate you participating in this discussion with us, Dawn, about the NIH's Inclusion across the Lifespan policy. For those interested, please do visit NIH’s grant webpage on inclusion for more information. This has been David Kosub with NIH's All About Grants. Thank you.

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