

Inclusion Across the Lifespan Case Studies

The Inclusion Across the Lifespan Policy requires research supported by the NIH to include individuals of all ages, unless there is a scientific or ethical reason not to include a specific age group. The case studies below provide examples that can help investigators examine whether their plans for age-specific exclusion criteria are justifiable according to NIH policy. See also the “Policy” section of the guide notice announcing the Inclusion Across the Lifespan policy, [NOT-OD-18-116](#).

Case #1:

An investigator is planning a study analyzing stress and anxiety levels in children involved in caregiving responsibilities for parents or younger siblings with cancer. The investigator will include standardized measures of stress and anxiety, observations of behavior, and review of the medical records for both the children and the family member with cancer.

The investigator plans to exclude individuals 60 years of age and over because the goal is to focus on parent/sibling relationships rather than grandparents. The investigator anticipates that most individuals under 18 will have parents below the excluded age range.

Considerations	Response
Is there a scientific reason for excluding specific age groups?	No
Is there an ethical reason for excluding specific age groups?	No

Take away: Age should only be used as an exclusion criterion when necessary. Rather than using age as exclusion criteria, the investigator can specify the types of relationships that allow individuals to be eligible for the study.

Case #2:

An investigator proposes a research project investigating the role of noise pollution on hypertension and food choices. The study is limited to individuals between the ages of 18 and 64. Participants will respond to survey questions and participate in focus groups. Participants in areas with high levels of noise pollution will be compared to participants in areas with low and moderate noise pollution levels.

The investigator chose to exclude children and older adults because children have less control over food choices, which they suspect may affect the study results. The researcher does not propose methods to address potential variability in study results among children, such as including parents in the research to provide additional context for the child’s environment. Regarding older adults, the investigator anticipated recruitment difficulties due to co-morbidities and residence in long-term or skilled care facilities limiting focus group participation and food choices.

Considerations	Response
Is there a scientific reason for excluding specific age groups?	No
Is there an ethical reason for excluding specific age groups?	No

Take away: Convenience is not a justifiable reason for excluding individuals based on age. While in some cases an age-specific study may be justifiable and warranted, investigators should consider designing their study in a way that is inclusive of all participants and consider working with colleagues and the community to assist in identifying what might be best for different study populations. Furthermore,

many children and older adults have control over their food choices. When exclusion is necessary, it should be limited to those populations that must be excluded.

Case #3:

An investigator plans a trial to test a new device to assist in mobility rehabilitation after stroke. The device, which is designed for individuals between 60 inches (127cm) and 80 inches (203cm) in height, is intended to increase physical strength and coordination, producing changes in gait. The investigator plans to limit the study to individuals over the age of 18, as stroke is rarely diagnosed in children, and children would not be able to use the device due to height requirements.

Considerations	Response
Is there a scientific reason for excluding specific age groups?	No
Is there an ethical reason for excluding specific age groups?	No

Take away: Age should only be used as an exclusion criterion when necessary. Considerations based on medical history, such as height/weight requirements, or other parameters, rather than age, should be examined. In this example, the condition being studied may occur in the excluded age group, and if present, those in the excluded age group may also require mobility rehabilitation. Rather than excluding based on age, necessary height requirements for use of the device may be more reasonable indications for excluding individuals. The investigator should consider the limitations of the device when designing the study and considering the potential public health impact.

Case #4

An investigator is testing a new medication for epilepsy. The medication was previously tested in adult populations but did not result in robust responses. The investigator believes that the medication would be metabolized differently in children, enhancing the benefits. Based on prior evidence indicating differences in metabolism, the investigator proposes limiting the study population to individuals under the age of 18. The investigator believes that studying the medication in children will provide new information about how the medication works, possibly creating an opportunity for modifications to be made that would benefit other age groups.

Considerations	Response
Is there a scientific reason for excluding specific age groups?	Yes
Is there an ethical reason for excluding specific age groups?	Yes

Take away: As stated in the policy, when “the knowledge being sought in the research is already available for the excluded age group, or will be obtained from another ongoing study, and an additional study will be redundant,” aged-based exclusion may be justified. In the case above, the investigator already had results from a study with the excluded age group. Likewise, the policy states that if “the study poses an unacceptable risk to the excluded group, such that their participation would not be considered ethical by the local IRB, peer review and/or NIH staff,” it may be justifiable to exclude based on age. Since the medication to be investigated was not beneficial to previously-exposed adults, including adults in the current study would likely raise safety and ethical concerns about their participation, without additional information and changes, such as dosing or method of administration, that could improve the results for adults.