## Inclusion Across the Lifespan: guidance for applying the policy

The Inclusion Across the Lifespan policy (IAL) applies to *all exempt and non-exempt human subjects research* (see NOT-OD-18-116), beginning with competing grant applications due *on/after January 25, 2019*, and R&D contract solicitations issued on/after this date.

For ongoing, non-competing awards, the <u>Inclusion of Children in Research</u>
<u>Policy</u> continues to be in effect.

## 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 to 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.

## \*Exclusion based on age must be due to ethical or scientific reasons. Acceptable justifications may include:

- The disease to be studied does not occur in the excluded age group
- The research topic is not relevant to the excluded age group
- Knowledge sought is already available for the excluded group
- Separate study for the excluded age group is warranted or preferable
- Research involves data from pre-enrolled participants
- Laws/regulations bar inclusion of individuals in a specific age group in research
- The study poses unacceptable risk to the excluded age group

For the purposes of the policy, a <u>child</u> is an individual under the age of 18. An <u>older adult</u> is an individual 65 years of age or older. For more information, visit the <u>Inclusion Across the Lifespan website</u>.