**Inclusion of Children Section for NIH grants**

**Goal: Justify the proposed age range for research participants**

NIH policy requires that applicants and grantees include children when conducting clinical research, unless there is a strong justification for their exclusion

A child is considered any individual under 18 years old; this age limit is effective as of January 25, 2016

If children will be included

* Describe and justify the age range(s) of individuals expected to be recruited
* Describe the team’s expertise in working with children of the included ages
* Describe facilities to accommodate children
* Indicate whether a sufficient number of children are included for a meaningful analysis relative to the purpose of the study

If children will be excluded

* Describe and justify the age range(s) of individuals expected to be recruited
* Describe and justify the exclusion of children under 18 or of a subset of children
	+ The research topic is irrelevant to children
	+ Laws or regulations prohibit inclusion of children
	+ The knowledge being sought is already available for children or is addressed by an ongoing study (provide references)
	+ A separate, age-specific study is warranted and preferable
	+ Insufficient data are available to assess potential risk in children

Check for policy updates and specific requirements

* <https://grants.nih.gov/grants/funding/children/children.htm>
* Application guide for your FOA/RFA will specify form page

**See the following page for a template and examples**

**Template**

**Inclusion of Children**

Minors will be (included/excluded) in the planned project. (In one sentence describe the study goals. Then provide justification for why minors younger than 18 years will be included or excluded from the study). In Oklahoma minors under the age of 18 will provide assent with parental consent.

(If children are included, describe the research team’s expertise in working with children of these ages and accommodations for children in the setting where the research will take place, such as specialized medical equipment, age-appropriate waiting areas, modifications to the study procedure, etc.)

**Example 1**

**Inclusion of Children**

Minors will be included in the planned project. This project focuses on understanding risk factors for obesity during early childhood. Therefore, the project will enroll children ages 2-5 years of age for assessment of height, weight, and selected biomarkers (see Research Plan). Parents of these children will be enrolled for assessment of height, weight, and socioeconomic, cultural and behavioral factors; it is possible that this will include minors under the age of 18. Whether enrolling as a young child or as a parent of a young child, all minors under the age of 18 will provide assent with parental consent, in accordance with Oklahoma state law.

The principal investigator is a board-certified pediatrician, and studies will take place in the clinic where the young children receive routine care.

**Example 2**

**Inclusion of Children**

Minors will be excluded from the planned project, as this study focuses on quality of life in geriatric patients with congestive heart failure.