## Inclusion of Children

Refer to [Supplemental Instructions, Part II](http://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/supplemental-instructions-forms-d.pdf%22%20%5Cl%20%224_1_protection_of_human_subject%22%20%5Ct%20%22_blank) ([Section 4.4](http://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/supplemental-instructions-forms-d.pdf%22%20%5Cl%20%224_4_inclusion_of_children%22%20%5Ct%20%22_blank) and [5.8](http://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/supplemental-instructions-forms-d.pdf%22%20%5Cl%20%225_8_nih_policy_on_inclusion_of%22%20%5Ct%20%22_blank)).

Create a section entitled “Inclusion of Children” and place it immediately following the section on the Inclusion of Women and Minorities. Although no specific page limits apply to this section of the application, be succinct. The NIH Policy on Inclusion of Children is referenced and described in [Part II Section 5.8](http://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/supplemental-instructions-forms-d.pdf#4_4_inclusion_of_children). For the purpose of implementing these guidelines, a child is now defined as an individual under the age of 18 years (for additional information see <http://grants.nih.gov/grants/funding/children/children.htm>

Scientific Review Groups will assess each application as being acceptable or unacceptable with regard to the age-appropriate inclusion or exclusion of children in the proposed research project. This section is required for all studies meeting the NIH definition for clinical research, not just clinical trials. It is important to provide a detailed plan of who will be included (and/or excluded) based on age. Details about why the individuals in the given age/age range are the appropriate individuals to accomplish the scientific goals of the study should be provided.

Instructions for this item of the Research Plan including addressing the following points:

* Describe the age(s) or age range of all individuals to be included in the proposed study.
* Specifically discuss whether children under the age of 18 (as a whole or a subset of individuals under 18) will be included or excluded.
* The description of the plan should include a rationale for selecting a specific age range of children.
* The plan also must include a description of the expertise of the investigative team for working with children at the ages included, of the appropriateness of the available facilities to accommodate the children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose of the study.
* When children are involved in research, the Additional Protections for Children Involved as Subjects in Research (45 CFR part 46 Subpart D) apply and must be addressed under the Protections Against Risk subheading (4.1.2.b).

**Justifications for Exclusion of Children**

For the purposes of this policy, individuals under 18 are defined as a child; however, exclusion of any specific age or age range group should be justified in this section. It is expected that children will be included in all NIHdefined clinical research unless one or more of the following exclusionary circumstances apply:

* The research topic to be studied is not relevant to children.
* Laws or regulations bar the inclusion of children in the research.
* The knowledge being sought in the research is already available for children or will be obtained from another ongoing study, and an additional study will be needlessly redundant. Documentation of other studies justifying the exclusions should be provided. NIH program staff can be contacted for guidance on this issue if the information is not readily available.
* A separate, age-specific study in children is warranted and preferable. Examples include:
	+ The condition is relatively rare in children, as compared to adults (in that extraordinary effort would be needed to include children, although in rare diseases or disorders where the applicant has made a particular effort to assemble an adult population, the same effort would be expected to assemble a similar child population with the rare condition); or
	+ The number of children is limited because the majority are already accessed by a nationwide pediatric disease research network; or
	+ Issues of study design preclude direct applicability of hypotheses and/or interventions to both adults and children (including different cognitive, developmental, or disease stages or different age-related metabolic processes). While this situation may represent a justification for excluding children in some instances, consideration should be given to taking these differences into account in the study design and expanding the hypotheses tested, or the interventions planned, to allow inclusion of children rather than excluding them.
* Insufficient data are available in adults to judge potential risk in children (in which case one of the research objectives could be to obtain sufficient adult data to make this judgment). Although children usually should Supplemental Grant Application Instructions II-17 not be the initial group to be involved in research studies, in some instances, the nature and seriousness of the illness may warrant their participation earlier based on careful risk and benefit analysis.
* Study designs are aimed at collecting additional data on pre-enrolled adult study subjects (e.g., longitudinal follow-up studies that did not include data on children).
* Other special cases can be justified by the investigator and assessed by the review group and the Institute/Center Director to determine if acceptable.