NIH Definitions: *Applicants/offerors for NIH funding are expected to justify the age range of the proposed participants in their clinical research, with particular attention paid to addressing the inclusion (or exclusion) of children (or subsets of children).*

*For more information on the child inclusion policy, see:*[*https://grants.nih.gov/grants/funding/children/children.htm*](https://grants.nih.gov/grants/funding/children/children.htm)

**Inclusion of Children (No Children)**

No children under the age of 18 will be recruited for the study. The exclusion of children is…

**Inclusion of Children**

Children under the age of 18 will be included in the study as participants, based on…

**Examples:**

Example 1:

Children will not be recruited for this study as ecopipam has not yet been studied in an open label fashion in that population. The exclusion of children is precautionary, as we are continuing to study the efficacy and tolerability of this compound in adults. A later project including children may be planned as data from adult studies become available.

Example 2:

Children under the age of 18 will not be recruited for this study, as age strongly influences status in both Pacific Islander and Asian American culture and communities. Children and youth in these communities are expected to defer to adults, including during group discussions and decision-making processes. Therefore, having a mixed-age group including children and youth under the age of 18 years and adults 18 years and older deliberate about the sensitive topic of substance use disorders would be likely to suppress the expression of dissenting views from the children and youth under the age of 18 years. For this reason, the inclusion of children under the age of 18 years into our research methodology was not recommended by our Samoan and Filipino cultural advisors.