

**Institutional Review Board (IRB) Resource Guide**

**FORM 6: RESEARCH INVOLVING CHILDREN/MINORS**

**\*\*If conducting a research study that may involve the recruitment and enrollment of anyone under the age of 18, you will need to provide additional documentation. Form 6 and Form 10 are requisite documents that will need to be submitted as part of your IRB proposal submission**

* Form 6 is a fillable, single-page PDF

**Form 6 subsections with helpful guidance:**

**Subsection A: State reason for including children/minors in your project:**

* While this information may already be included in your Form 1, you will need to state in section A the reasons for including minors in your study as research participants

**Subsection B: Risk categorization**

* In section B, you will be asked to categorize your proposed research project based on the provided choices related to Minimal Risk
  + Minimal risk means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests
* You will need to answer the questions that correspond to the category selected
  + If you select CRL #1 or CRL #2, both assent of the child and permission of at least one parent or guardian is required
  + If you select CRL #3, permission must be obtained from both parents unless there is only one reasonable available parent. Guardian consent should be substituted for parental under appropriate legal constraints
  + If you select CRL #4, your proposal will be need to be submitted for a ruling by the Secretary of DHHS following consultation with an appropriate panel of experts