

# North Texas Regional Institutional Review Board

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## *Guidance and Procedures for Investigators*

### **Topic: When Minors become Adults (during a research study)**

In studies involving children (generally speaking, anyone under age 18), the parent gives permission for the child to participate via a Parental Permission Form, and the child must also “assent” to be in that research project, again via a Child/Adolescent Assent Form. In some cases, the study continues long enough for that child to turn age 18 or otherwise become an adult (marriage, enlistment in armed forces, etc.). When a child research subject becomes an adult, and is still involved in that research study, regulations require that former child (now an adult) to “re-consent,” now as an adult, to continue to participate in research. Usually this is done with a re-consenting process using an adult consent form, indicating that the child-now-adult has full legal decision-making authority and responsibility for their involvement in the project.

### Re-Consenting Minors

Investigators who conduct research with children, particularly adolescents, should come up with an appropriate plan for re-consenting these subjects (i.e., children who become adults while participating). The plan for re-consenting should be described in the protocol synopsis.

The parental permission form and the child/adolescent assent form should mention that minor participants will be re-consented as adults when they turn 18 years of age.

Some examples of language to include in the protocol synopsis, parental permission form, and the child/adolescent assent form are provided (below).

- Information to include in the Protocol Synopsis:

“Participants enrolled in this study as minors will be re-consented as adults when they turn 18 years old if they are still actively participating in this study. Re-consenting will occur at the next available opportunity (i.e. next study visit, contact point, intervention, etc.) upon reaching majority.

- Statement to include in the Parental Permission Form:

“If your child becomes an adult (turns 18 years old) while they are still actively participating in this research, we will request that he or she provide their consent (agreement) to continue their participation in this study.”

- Statement to include in the Child/Adolescent Assent Form:

“If you become an adult (turn 18 years old) during this study, we will ask you if you want to continue to be in this study as an adult.”