

## North Texas Regional Institutional Review Board

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### *Guidance and Procedures for Investigators*

#### **Topic: Re-Consenting Subjects**

Federal regulations do not require re-consenting of subjects who have *completed* their active participation in the study, or of subjects who are still actively participating, *when the proposed change will not affect their participation*. However, when changes do occur in the conditions or the procedures of a study that would affect an individual subject, the investigator should once again seek informed consent from the subjects. Those subjects who are presently enrolled and actively participating in the study should be informed of the change and re-consented if it might relate to the subjects' willingness to continue their participation in the study. Adverse events may occur during a research activity that would directly affect whether prospective or enrolled subjects would wish to continue in a particular research activity. The IRB does not require a subject re-consent at the time of the protocol continuation approval, *unless there have been modifications to the consent form that would affect an individual subject*. Study participants who are minors and actively participating in a study should be re-consented as adults when they turn 18 (see the NTR IRB Standard Operating Principles and Procedures Manual for detailed information).