**ADDENDUM:** **CERTIFICATE OF CONFIDENTIALITY CONSENT Language**

**If a study is funded by NIH or a CoC has been obtained from the NIH Kiosk insert the following language into the section AFTER ‘How will information about me be kept private or confidential?’**

**Replace instructional language (in BLUE) with language that applies to your research.**

**If this is inserted into a Parental/Guardian Permission form,**

* **change “consent” to “parental/guardian permission”**
* **change “you” to “your child” where appropriate**
* **change “me” or “my” to “your child(‘s)” where appropriate**

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.