Effective May 1, 2012, applications for new studies submitted to the IRB will no longer require an Assent Form for subjects 7 through 11 years old. Assent for this age group will instead be documented on the Informed Consent/Parental Permission form. The Principal Investigator or other individual obtaining informed consent and assent will sign an **Affidavit of Person Obtaining Assent** at the end of the Informed Consent/Parental Permission form template. The affidavit attests that the study was explained to the child to the best of his or her ability to understand, all of the child’s questions were answered, and the child voluntarily agreed to participate in the study. (See new template language below.) The signatures of children 7 through 11 years old will not be required.

Assent by 12 through 17 year-olds will continue to be documented by having the subject sign an age-appropriate Assent Form.

What is being added to the Informed Consent/Parental Permission document?
The following affidavit will become part of the standard Informed Consent/Parental Permission template. (This text may be deleted from the template if the study population will not include children ages 7 through 11.)

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### AFFIDAVIT OF PERSON OBTAINING ASSENT FOR CHILDREN 7-11 YEARS OLD:

I have explained all aspects of the research study to the child participant to the best of his/her ability to understand.

I have answered all of the child participant’s questions relating to the research study.

I believe the child participant’s decision to enroll is voluntary. I have explained to the child participant that he/she can withdraw from the research study at anytime.

The study doctors and study staff agree to respect the child participant’s physical or emotional dissent at any time during this research study when that dissent pertains to anything being done solely for the purpose of the research.

Printed Name of Individual Obtaining Assent: ________________________________

Title: _______ Signature: ________________________________ Date: __________
obtained from children capable of providing it. The regulations do not require, however, that assent be documented in writing. It has been the policy of Children’s National for many years to require separate documents to record child assent beginning at age 7 until the age of majority (18 years). Experience has shown us, however, that requiring that a separate assent form be signed by children ages 7 through 11 does not provide any additional protections for this vulnerable population. The IRB Executive Committee concluded that researchers can comply with the Federal regulations regarding assent in a manner that is more sensitive to the young child as well as more practical if the requirement to obtain signatures from 7 through 11 year-olds is eliminated.

What are the requirements for new studies?
Studies submitted to the IRB beginning May 1, 2012, will no longer require a separate assent form for children 7 through 11 years of age. For studies enrolling children under the age of 12, the informed consent/parental permission form must include new affidavit template language verifying that assent was obtained. This statement must be signed at the time of the child’s assent by the PI or other individual who obtains the assent.

What are the requirements for existing (approved) studies?
Initially, investigators with existing studies can continue to use their previously approved informed consent/parental permission and 7-11 assent forms. Investigators are required to follow the new assent documentation requirements for existing studies ONLY if they are requesting other consent/parental permission and/or assent form changes as part of an amendment, or if the IRB issues contingencies requiring other consent/parental permission and/or assent form changes when it reviews an amendment or continuing review submission. If no other changes to these documents are requested by the investigator or required by the IRB, the current consent/parental permission and assent forms can still be used.

Investigators who want to adopt the new assent documentation procedure for their existing studies more immediately may submit an amendment to request IRB approval specifically for that change at any time. *Formal IRB approval must be obtained before any changes to the study protocol can be implemented.*

What if I have or want to obtain a waiver of assent for my study?
The revised policy does not affect waivers of assent. If the PI does not anticipate that subjects ages 7 through 11 years will have the capacity to give assent for their participation, he or she may apply to the IRB for a waiver of assent. If a waiver has been granted for this age group, the statement in the informed consent/parental permission form verifying assent need not be included. If the waiver is only applicable to some of the 7 through 11 year-old subjects, the statement should be included in the consent document. It is recommended that the person obtaining consent make a notation on the form when assent is waived for a specific individual and state the justification (e.g., the child lacks the cognitive capacity to give assent).