I. POLICY

Investigators are responsible for developing an informed consent process and method of documentation appropriate to the type of research and the study population, emphasizing the importance of subject comprehension and voluntary participation.

II. ACCOUNTABLE EXECUTIVE AND REVIEWER(S)

A. Accountable Executive: Chief Academic Officer/Institutional Official for the Federalwide Assurance
B. Department Responsible for Review: Office for the Protection of Human Subjects
C. Committee Responsible for Review: Institutional Review Board Executive Committee
   Research Policy/Procedure Working Group

III. APPROVAL

Approved by:

__________________________  ____________________________
IRB Executive Committee  10/01/2009  Date

__________________________
Research Policy/Procedure Working Group  Date

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Mark L. Batshaw, M.D., Chief Academic Officer  Date
IV. **APPLICABILITY**

Areas where the policy and procedure applies: Children's Research Institute, Children’s National Medical Center

Persons to whom the policy and procedure applies: Investigators, research staff

V. **REVIEW OR REVISION DATE**

Original:

VI. **REFERENCES**

AAHRPP Element(s):

Federal Regulations: U.S. Department of Health and Human Services (DHHS) 45 CFR 46.116; 45 CFR 46.408 (Subpart D)
Food and Drug Administration (FDA) 21 CFR 50.20; 21 CFR 50.55)

Policies and Procedures: RA:HRPP:07.02 and 07.02P, *Informed Consent/Parental Permission and Assent Process*
RA:HRPP:07.03 and 07.03P, *Documentation of Informed Consent/Parental Permission and Assent*
I. **PROCEDURE**

A. Investigators are responsible for obtaining legally effective informed consent from the subject or the subject’s legally authorized representative unless the Institutional Review Board (IRB) has granted an alteration or waiver of informed consent. (45 CFR 46.116; 21 CFR 50.20)

B. In addition, investigators are responsible for obtaining the assent of all subjects who are children unless the IRB has granted an alteration or waiver of assent. (45 CFR 46.408 (Subpart D); 21 CFR 50.55)


II. **REVIEW OR REVISION DATE**

Original:

III. **REFERENCES**

AAHRPP Element(s):

Federal Regulations: U.S. Department of Health and Human Services (DHHS) 45 CFR 46.116; 45 CFR 46.408 (Subpart D)

Food and Drug Administration (FDA) 21 CFR 50.20; 21 CFR 50.55

Policies and Procedures: RA:HRPP:07.02 and 07.02P, *Informed Consent/Parental Permission and Assent Process*

RA:HRPP:07.03 and 07.03P, *Documentation of Informed Consent/Parental Permission and Assent*
RA:HRPP:07.04 and 07.04P, *Waivers and Alterations of Informed Consent/Parental Permission*
RA:HRPP:07.05 and 0.705P, *Obtaining Informed Consent/Parental Permission and Assent via Telephone and Mail*