SUBJECT: Investigator Responsibilities for Prospectively Obtaining Legally Effective Informed Consent

POLICY: RA:HRPP:10.09

DATE EFFECTIVE:

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

_____ — _____
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*

SUBJECT: Investigator Responsibilities for Prospectively Obtaining Legally Effective Informed Consent

PROCEDURE: RA:HRPP:10.09P

DATE EFFECTIVE:

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)

C. Specific policies and procedures are described in 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*, and RA:HRPP:07.05 and 0.705P, *Obtaining Informed Consent/Parental Permission and Assent via Telephone and Mail*.

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*