SUBJECT: Investigator Responsibilities for Reporting Unanticipated Problems

POLICY: RA:HRPP:10.10

DATE EFFECTIVE:

I. POLICY

Investigators must assess and report unanticipated problems involving risk to research subjects or others occurring during a research study in accordance with applicable Federal, State, and local regulations and with Children's National Medical Center Human Research Protection Program (HRPP) policies and procedures.

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

V. REVIEW OR REVISION DATE

Original:

VI. REFERENCES

AAHRPP Element(s):

Federal regulations: U.S. Department of Health and Human Services (DHHS) 45 CFR 46.103(b)(5)(i)
Food and Drug Administration (FDA) 21 CFR 56.108(b)(1)

Office of Human Research Protection (OHRP) Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events

Policies and Procedures: RA:HRPP:06.02 and 06.02P, *Unanticipated Problems Involving Risks to Subjects or Others, Including Adverse Events*

SUBJECT: Investigator Responsibilities for Reporting Unanticipated Problems

PROCEDURE: RA:HRPP:10.10P

DATE EFFECTIVE:

I. PROCEDURE

A. Investigators and research staff should understand the distinction between "Unanticipated Problems Involving Risks to Subjects or Others" (UPIRTSOs) and "adverse events."

B. The types of events that must be reported by investigators to the Institutional Review Board (IRB), and the procedure for making these reports are found in RA:HRPP:06.02 and 06.02P, *Unanticipated Problems Involving Risks to Subjects or Others, Including Adverse Events*.

II. REVIEW OR REVISION DATE

Original:

III. REFERENCES

AAHRPP Element(s):

Federal regulations: U.S. Department of Health and Human Services (DHHS) 45 CFR 46.103(b)(5)(i)
Food and Drug Administration (FDA) 21 CFR 56.108(b)(1)

Office of Human Research Protection (OHRP) Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events

Policies and Procedures: RA:HRPP:06.02 and 06.02P, *Unanticipated Problems Involving Risks to Subjects or Others, Including Adverse Events*