I. POLICY

The Principal Investigator must determine that the resources necessary to protect human subjects are present before conducting a research study.

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

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 and research staff, Institutional Review Board, Office for the Protection of Human Subjects

V. REVIEW OR REVISION DATE

Original:

VI. REFERENCES

AAHRPP Element(s):
I. **PROCEDURE**

A. When conducting a research study, investigators should have the resources necessary to protect human participants, including:

1. Sufficient time to conduct and complete the research;

2. A process to ensure that all persons assisting with the research are adequately informed about the protocol and their research-related duties and functions;

3. Access to a population that will allow recruitment of the necessary number of subjects.

B. Investigators are to conduct research only with resources that are appropriate to ensuring research subject safety.

C. Investigators should not commence a research study without adequate resources to protect subjects, and should stop a research study if resources become unavailable.

II. **REVIEW OR REVISION DATE**

Original:

III. **REFERENCES**

AAHRPP Element(s):