



SUBJECT: Investigator Resource Requirements
for Protecting Human Subjects

POLICY: RA:HRPP:10.08

DATE EFFECTIVE:

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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

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

V. REVIEW OR REVISION DATE

Original:

VI. REFERENCES

AAHRPP Element(s):



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PROCEDURE: RA:HRPP:10.08P

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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):