



SUBJECT: Investigator, Study Staff, and Family
Member Conflicts of Interest (COI)

POLICY: RA:HRPP:10.04

DATE EFFECTIVE:

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I. POLICY

Conflicts of interest for investigators, members of the study staff, and family members of the investigators and study staff must be disclosed to the Children's National Medical Center (CNMC) Institutional Review Board (IRB) for review to assure elimination or appropriate management of the conflict.

The convened IRB has the final authority to decide whether the interest and its management, if any, allow the research to be approved.

Definition

Family member, for the purpose of this policy and procedure, means spouse and dependent children.

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, and their family members

V. REVIEW OR REVISION DATE

Original:

VI. REFERENCES

AAHRPP Element(s):

Policies and Procedures: CNMC C-14 and C-14P, *Conflict of Interest*



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I. PROCEDURE

- A. It is the Principal Investigator's responsibility to assure all conflicts of interest are properly disclosed as required by Children's National Medical Center (CNMC) policy.
- B. All applicable financial interests are to be disclosed by faculty members and research staff annually, as per CNMC policy C-14 and C-14P, *Conflict of Interest*. The CNMC Corporate Compliance Officer will report to the IRB any disclosures of significant conflict of interest that may be relevant to human subjects research conducted at the institution.
- C. Study-specific financial interests are to be disclosed for each individual listed on Form 1572 or its equivalent whenever a protocol is submitted to the office of Grants and Contracts Administration.
- D. For studies reviewed at a fully convened meeting, the IRB will determine whether any reported conflict of interest has been adequately eliminated or managed. The board may require additional measures to manage the conflict prior to taking final action on the proposed research. The IRB Chair or his/her designee will make a similar determination for studies reviewed using an expedited process.

II. REVIEW OR REVISION DATE

Original:

III. REFERENCES

AAHRPP Element(s):

Policies and Procedures: CNMC C-14 and C-14P, *Conflict of Interest*

Forms: Study-Specific Conflict of Interest Disclosure Form