I. POLICY

All individuals engaged in the conduct of human subjects research under the jurisdiction of the Children’s National Medical Center (CNMC) Institutional Review Board (IRB) must have appropriate expertise, meet applicable CNMC credentialing qualifications, and be knowledgeable about human subject protections.

The human research protection program at CNMC relies on the professional standards as required by the Joint Commission for Accreditation of Hospitals. These standards assure that CNMC employees engaged in research involving medical interventions are capable of maintaining patient care standards and oversight of the quality of care, treatment, and services rendered by practitioners privileged through the medical staff process.

Only individuals who have been granted an appointment to the Medical Staff and clinical privileges to attend patients in Children’s Hospital and its other facilities may conduct medical interventions or procedures as part of human subjects research at CNMC.

This policy applies to principal investigators (PIs) and all other members of the research team regardless of the location of the research or the source of financial support.

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
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 staff who conduct human subjects research

V. **REVIEW OR REVISION DATE**

Original:

VI. **REFERENCES**

AAHRPP Element(s):

Medical Staff Bylaws, Standard MS.02.01.01
Nursing Research Policy and Procedure
I. **PROCEDURE**

A. All individuals conducting human subjects research must be adequately qualified and licensed relevant to the scope and complexity of the research conducted.

B. Eligibility to be a Principal Investigator (PI)

The Children’s National Medical Center (CNMC) Institutional Review Board (IRB) will permit human subjects research to be conducted on CNMC premises only if the Principal Investigator (PI) has an appointment to the appropriate staff of Children’s Hospital or meets certain departmental requirements approved by the IRB.

1. **Faculty:** Research protocols may be submitted for IRB review by individuals at Children's National Medical Center who have a primary or secondary appointment in the Department of Pediatrics at George Washington University.
   
   a) An individual’s Faculty appointment must be at the level of Assistant Professor or above for the individual to be eligible to be a Principal Investigator.
   
   b) The records of the CNMC Medical and Academic Affairs Department will be considered determinative in establishing the existence and scope of an individual’s faculty appointment.

2. **Adjunct Faculty:** Individuals whom are identified in the records of the Medical and Academic Affairs Department as CNMC adjunct faculty (i.e., holding an academic appointment at an institution other than George Washington University) are eligible to submit a study for IRB review as the PI only after the following three-step process has been completed:
   
   a) The Clinical Division Chief or Director of the Research Center to which the adjunct faculty member is assigned or his/her equivalent must pre-review the research protocol to verify the adjunct faculty member’s qualifications, feasibility of the study, and adequacy of departmental resources to conduct the study.
   
   b) The Clinical Division Chief/Research Center Director or his/her equivalent must issue a written statement that the PI then submits to
the IRB, documenting division/center approval and verifying that the individual is qualified to conduct the research.

3. **Non-Faculty**: The IRB will permit CNMC employees and staff without a faculty appointment to serve as the Principal Investigator of a *minimal risk protocol* provided criteria a) and b) below are sufficiently met. They are as follows:
   a) The CNMC department to which the employee is assigned must provide to the IRB a plan that includes a body or individual that is responsible for pre-review of each research study to verify the non-faculty member’s qualifications, the feasibility of the study, and adequacy of departmental resources to conduct the study.
   b) The departmental pre-review must result in the issuance of a written statement that the PI then submits to the IRB documenting departmental approval and verifying that the individual is qualified to conduct the research.
   c) Item b) above must be provided to the IRB as attachments for each protocol submitted to the IRB for review in order to maintain complete documentation for the study.
   d) The plan developed by the Department of Nursing includes the appointment of a faculty member to serve as a mentor for the PI who is not a faculty member. A full description of the Nursing Department model is in Nursing Research Policy and Procedure.

4. The IRB recognizes one Principal Investigator for each project. The Principal Investigator bears the ultimate responsibility for assuring that the conduct of the study complies with all CNMC Human Research Protection Program (HRPP) policies and procedures.

5. When the Principal Investigator for a protocol involving an investigational agent(s) does not have a medical degree (M.D.), there must be at least one co-investigator on the project that is a qualified M.D. with the appropriate expertise for the study.

6. Students and fellows are not permitted to be Principal Investigators.
   a) All students and fellows applying for IRB review must have a faculty member serve as the Principal Investigator.
   b) All activities that meet the definition of research with human subjects and that are conducted by students must be reviewed by the IRB.
   c) Activities that must be reviewed and approved by the IRB include:
      i. All master’s theses and doctoral dissertations that involve human research subjects; and
      ii. All class or other projects that meet the definition of human subjects research.
7. Failure to observe the policies and procedures of the CNMC IRB and Human Research Protections Program will be considered serious misconduct subject to sanctions, including possible termination of faculty appointment or other affiliation with CNMC.

C. Researcher Medical Qualifications

1. Appointments to the Children’s Hospital Medical Staff with clinical privileges are granted by the Hospital Board of Directors in accordance with the Medical Staff Bylaws (Standard MS.02.01.01).

2. The categories of clinical appointment to the Medical Staff include Attending, Consulting, Allied Doctoral Clinician, Allied Health Professional, and Limited Duty.

3. Any researcher to whom clinical privileges have been granted is considered to be medically credentialed to conduct the same privileges in a research setting.

4. As part of the Institutional Review Board (IRB) review of a research proposal, the Board will determine if individuals who are designated to conduct any medical interventions or procedures (ranging from medical histories and physical examinations to an invasive medical procedure) as part of the research have the appropriate medical credentials to protect research subjects.

5. If the IRB has any concerns regarding a researcher’s qualifications, it may request that the PI provide documentation and verification of a medical appointment with clinical privileges that correspond with the research interaction planned with participants. The research may not proceed until verification is received.

D. Knowledge of Human Research Protections

CNMC requirements for training in human subjects protection for all persons involved in conducting research are described in RA:HRPP:10.3 and 10.3P, Education and Training: Investigators and Research Staff.

II. REVIEW OR REVISION DATE

Original:

III. REFERENCES

AAHRPP Element(s):

Medical Staff Bylaws, Standard MS.02.01.01
Nursing Research Policy and Procedure