I. POLICY

When reviewing human subject research protocols, the Children’s National Medical Center (CNMC) Institutional Review Board (IRB) evaluates the proposed arrangements for protecting the privacy interests of research subjects during and after their involvement in the research.

The IRB also evaluates the proposed arrangements for protecting the confidentiality of identifiable data, when appropriate, during and after the conclusion of the study.

Definitions

Privacy: Refers to persons and their interest in controlling the access of others to themselves. For example, based on their privacy interests, people want to control:

- The time and place where they give information;
- The nature of the information they want to give;
- The nature of the experiences that are given to them;
- Who receives and can use the information

Confidentiality: Refers to the maintenance of the investigator’s agreement with the subject about how the subject’s identifiable private information will be handled, managed, and disseminated.

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  3/8/2010

____________________________  Date
Mark L. Batshaw, M.D., Chief Academic Officer

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: Institutional Review Board, investigators

V. REVIEW OR REVISION DATE

Original:

VI. REFERENCES

AAHRPP Element(s):

Food and Drug Administration (FDA) 21 CFR 56.111(a)(7)
I. **PROCEDURE**

A. One of the regulatory criteria for Institutional Review Board (IRB) approval of human subject research is that there are adequate provisions to protect the privacy interests of subjects and to maintain the confidentiality of identifiable data. (See U.S. Department of Health and Human Services 45 CFR 46.111(a)(7); Food and Drug Administration 21 CFR 56.111(a)(7))

B. Investigators must describe fully in their protocol applications all provisions to protect subjects’ privacy interests and maintain data confidentiality.

1. What is private depends on the individual and can vary according to gender, ethnicity, age, socio-economic class, education, ability level, social or verbal skill, health status, legal status, nationality, intelligence, personality, and the individual’s relationship to the investigator. For example, protecting the privacy interests of a young child might mean having a parent present at a session with an investigator. Protecting the privacy interests of a teenager might mean having a parent absent.

2. When appropriate, a Certificate of Confidentiality may be used to maintain the confidentiality of identifiable data (RA:HRPP:08.11 and 08.11P, *Certificates of Confidentiality*). Other methods of storage, handling, and sharing of data that can be used to protect confidentiality include using passwords on data files, locking filing cabinets that contain data, inter-file linkage, error inoculation, top coding, bracketing, and data brokering.

C. Members of the IRB should understand the concepts of privacy and confidentiality, and how they differ. Members should know strategies to protect privacy interests relating to contact with prospective subjects and access to private information. They should also be knowledgeable about strategies to maintain confidentiality of identifiable data, including controls on storage, handling, and sharing of data. The IRB must determine that the provisions to protect subject privacy and data confidentiality proposed by the investigator are adequate before approving any research.
II. REVIEW OR REVISION DATE

Original:

III. REFERENCES

AAHRPP Element(s):

   Food and Drug Administration (FDA) 21 CFR 56.111(a)(7)

Policies and Procedures: RA:HRPP:08.11 and 08.11P, *Certificates of Confidentiality*