SUBJECT: Medical Record and Database Review **POLICY:** RA:HRPP:09.05

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I. POLICY

It is the policy of Children's National Medical Center (CNMC) that the Institutional Review Board (IRB) will review and approve all medical record reviews and database requests that are performed for research purposes. The purpose of the review is to provide additional safeguards and protections for the confidentiality of the data.

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 3/22/2010
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, Institutional Review Board

V. REVIEW OR REVISION DATE

Original:

VI. REFERENCES

AAHRPP Element(s):

SUBJECT: Medical Record and Database Review **PROCEDURE:** RA:HRPP:09.05P

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I. PROCEDURE

A. Investigators who are planning research where hospital records and databases will be accessed first must receive Children's National Medical Center (CNMC) Institutional Review Board (IRB) approval. Hospital-based medical records sources at CNMC create an audit trail of access activities.

B. Investigator Requirements

1. Investigators must provide the following information in their IRB protocol application:
    a) Who will perform the review;
    b) The purpose of the review;
    c) Who will have access to the information;
    d) What the information will be used for;
    e) The steps that will be taken to protect confidentiality;
    f) The period of time for which the records will be reviewed (e.g. records of patients seen from March through September, 2009)

2. Investigators must provide information to assure compliance with the HIPAA regulations.

3. Investigators must provide sufficient information for it to be determined whether the proposed activity constitutes research with human subjects, whether it may be exempt from review, or whether expedited review is appropriate.

4. Investigators may apply for a waiver of informed consent requirements, if appropriate. The IRB will consider the waiver request in accordance with federal regulations 45 CFR 46.116(d) and 45 CFR 46.117.

C. IRB review is required for all research-related medical record reviews and database requests for research, regardless of whether the investigator wishes to maintain an identifier or a link to an identifier.

D. Upon receiving a submission for retrospective medical record or database review, the IRB Regulatory Analyst assesses the application for completeness and clarifies any remaining issues with the investigator. A preliminary determination

is made as to whether the activity constitutes human subject research, whether the activity is exempt, or whether expedited review is appropriate.

E. The type of information under review, where and how the data will be stored, who will have access to it, who is responsible for maintaining it, and the steps taken to maintain confidentiality are also considered during the review.

F. Once the IRB Analyst completes the review, the IRB Chair makes the final determination whether the protocol meets the definition of human subjects research. If it does, the Chair then determines whether the study is eligible for exemption, or if it meets criteria for review using the expedited process. Activities that are not human subject research will not require any additional follow-up. Exemptions will follow the policy and procedures found in RA:HRPP:05.03 and 05.03P, *Exempt Research*.

G. For those studies that are determined to be expeditable, approval is valid for a period of one year. Investigators are sent notification 90 days prior to expiration and are required to submit a continuing review form if the research is to continue. (See RA:HRPP:05.08 and 05.08P, *Continuing Review and Study Closure*)

II. REVIEW OR REVISION DATE

Original:

III. REFERENCES

AAHRPP Element(s):

Policies and Procedures: RA:HRPP:05.03 and 05.03P, *Exempt Research*
RA:HRPP:05.08 and 05.08P, *Continuing Review and Study Closure*