DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control and Prevention

National Center for Health Statistics
3311 Toledo Road, Room 1209
Hyattsville, Maryland 20782

MEMORANDUM

February 4, 2008

From: Stephen Blumberg, Ph.D.
Chair, NCHS Research ERB
Anjani Chandra, Ph.D.
Co-Chair, NCHS Research ERB

Protocol #2008-04 Pilot Test for a Redesign of the National Hospital Discharge Survey

To: Catharine Burt, Ed.D.

The NCHS Research Ethics Review Board reviewed the request for new Protocol #2008-04 Pilot Test for a Redesign of the National Hospital Discharge Survey on January 16, 2008 using the review process based on 45 CFR 46.

Protocol #2008-04 is approved for the maximum allowable period of one year.

IRB approval of protocol #2008-04 will expire on 01/16/2009.

If it is necessary to continue the study beyond the expiration date, a request for continuation approval should be submitted about 6 weeks prior to 01/16/2009.

There is no grace period beyond one year from the last approval date. In order to avoid lapses in approval of your research and the possible suspension of subject enrollment, please submit your continuation request at least six (6) weeks before the protocol's expiration date of 01/16/2009. It is your responsibility to submit your research protocol for continuing review.

The Board voted (12-0) that the protocol represent a no greater than minimal risk to the participants.

The Board voted (12-0) In accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Regulation (45 CFR 164.512), the Board voted to approve a waiver of patient authorization for release of patient medical record data by health care providers. The Board determined that the disclosure of protected health information involves no more than a minimal risk to privacy of individuals. The Board determined that:

a. There was an adequate plan to protect the identifiers from improper use and disclosure,
b. There was an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, and that an adequate research justification was provided for retaining the following identifiers: name, address, zip code, date of birth, date of admission, date of discharge, dates of procedure, Social Security Number, medical record number, and Medicare health insurance benefit / claim number and
c. There were adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by this subpart. The Board also agreed that the research could not practicably be conducted without the waiver. The Board agreed that the research could not practicably be conducted without access to and use of the protected health information.

In accordance with 45 CFR 46.116(d), the Board voted (12-0) to approve a waiver of the requirements to obtain informed consent of patients. The Board determined that the study would pose no greater than minimal risk to participants and that omission of the consent process would not adversely affect the rights or welfare of the subjects. The Board agreed that it would not be practicable for the investigators to contact patients, the next of kin, or their legal guardians before obtaining

the data. The Board decided the fourth criterion did not apply to this situation. The Board recognized that information about the research is available from a number of sources.

Any problems of a serious nature resulting from implementation of this protocol should be brought to the attention of the Research ERB, and any proposed changes should be submitted for Research ERB approval before they are implemented.

Please submit "clean" copies of the revised protocol, consent forms, and any other revised materials to this office for the official protocol file.

Please call me or Dewey LaRochelle if you have any questions.

Stephen Blumberg, Ph.D.
Chair, NCHS Research ERB

Anjani Chandra
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