



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Disease Control and Prevention

National Center for Health Statistics
3311 Toledo Road, Room 7107
Hyattsville, Maryland 20782

Date: April 27, 2012

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

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To: Carol DeFrances, Ph.D.

Subject: Protocol #2009-21 "National Hospital Care Survey", Amendment #6 "Pretest collection of ambulatory care data"

The NCHS Research Ethics Review Board (ERB) reviewed the request for amendment of Protocol #2009-21 National Hospital Care Survey, Amendment #6 "Pretest collection of ambulatory care data" on April 18, 2012, using the review process, based on 45 CFR 46.

Description of proposed modification:
Amendment #6 "Pretest collection of ambulatory care data"

Of Note: Please consider rewording your advance letter. As it is currently written, a hospital may be left with the impression that they are the only hospital being asked to participate, rather than being one of several.

Protocol #2009-21 Amendment #6 is approved.

In addition, the convened Board agreed to grant the following waivers to Protocol #2009-21 National Hospital Care Survey under normal review procedures:

- 1) In accordance with 45 CFR 46.116(d), the Board voted 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.
- 2) 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. The Board determined that the disclosure of protected health information involves no more than a minimal risk to privacy of individuals.

IRB approval of protocol #2009-21 will expire on **09/16/12**.

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 09/16/12.

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 09/16/12. It is your responsibility to submit your research protocol for continuing review.

Any problems of a serious nature resulting from implementation of these changes should be brought to the attention of the Research ERB, and any additional proposed changes should be submitted for IRB 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 Verita Buie, Dr.P.H. if you have any questions.

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