



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Disease Control and Prevention

National Center for Health Statistics
3311 Toledo Road, Room 7115
Hyattsville, Maryland 20782

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

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To: Carol DeFrances, Ph.D.
Sonja Williams

Subject: New Protocol #2015-13 National Hospital Care Survey

The NCHS Research Ethics Review Board reviewed the request for new Protocol #2015-13 National Hospital Care Survey, using the full board review process based on 45 CFR 46. Protocol #2015-13 is approved for the maximum allowable period of one year.

In addition, the Convened Board agreed to grant the following waivers to Protocol #2015-13 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.
- 3) In accordance with 45 CFR 46.116(d), the Board voted to approve a waiver of the requirements to obtain informed consent of physicians. 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.

ERB approval of protocol #2015-13 will expire on 09/16/16.

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 09/16/16.

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 09/16/16. 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 ERB approval before they are implemented.

Please call me or Andrea MacKay, M.S.P.H., if you have any questions.



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