DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control and Prevention

National Center for Health Statistics
3311 Toledo Road
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From: Lara Akinbami, MD
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Protocol #2003-05 National Ambulatory Medical Care Survey

To: Catharine Burt, Ed.D.

The NCHS Institutional Review Board reviewed the request for continuation of Protocol #2003-05 National Ambulatory Medical Care Survey, using the review process, based on 45 CFR 46. In addition, the Board considered the protocol as affected by the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

The NCHS IRB approved the continuation of Protocol #2003-05 National Ambulatory Medical Care Survey for the maximum allowable period of one year.

In addition, the convened Board agreed to continue the following waivers granted to Protocol #2003-05 National Ambulatory Medical 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. The Board noted that the data are already collected and contained in the medical records and no directly identifying data are collected. The Board also 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.
2) In accordance with 45 CFR 46.117(c)(2), the Board voted to approve a waiver of the documentation of informed consent by physicians. The Board determined that the research presents no more than minimal risk of harm to subjects and involves no procedure for which written consent is normally required outside of the research context. The Board also recognized that the investigators provide the physicians with written statements and other information regarding the research.
3) 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: date of birth, date of health care visit, and zip code, 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.

IRB approval of protocol #2003-05 National Ambulatory Medical Care Survey will expire on 02/12/2006.

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 02/12/2006.

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 02/12/2006. It is your responsibility to submit your research protocol for continuing review.

Any problems of a serious nature resulting from implementation of this protocol should be brought to the attention of the IRB, and any 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 Dewey LaRochelle or me if you have any questions.

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