**DEPARTMENT OF HEALTH & HUMAN SERVICES**

**Public Health Service**
**Centers for Disease Control and Prevention**

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

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

Protocol #2005-11 National Survey of Ambulatory Surgery

To: Robert Pokras, M.A.

The NCHS Institutional Review Board reviewed the request for new protocol #2005-11 National Survey of Ambulatory Surgery, using the review process, based on 45 CFR 46,.

The NCHS IRB approved Protocol #2005-11 National Survey of Ambulatory Surgery on August 25, 2005. The Board determined (6-0) that the study would pose a no greater than minimal risk to participants.

The Board granted the following waiver to Protocol #2005-11 National Survey of Ambulatory Surgery as required by HIPAA's Privacy Rule (45CFR164.152):

1) In accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Regulation (45 CFR 164.512), the Board approves (6-0) 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: exact date of visit, birth date, and zip code.
    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.
2) The Board agreed that the research could not practicably be conducted without the waiver.
3) The Board also agreed that the research could not practicably be conducted without access to and use of the protected health information.

The Board also granted a waiver of informed consent from patients under 45 CFR 46.116(d). The Board voted (6-0) to approve the request for waiver of the requirements to obtain informed consent. The Board found that:

1) The research involves no more than minimal risk to the subjects.
2) The waiver or alteration will not adversely affect the rights and welfare of the subjects.
3) The research could not practicably be carried out without the waiver.
4) The Board decided the fourth criterion for altering or waiving the informed consent process did not apply to this situation.

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

Stephen Blumberg, Ph.D.
Co-Chair, NCHS IRB