WAIVER OF INFORMED CONSENT

The ERB granted the National Hospital Ambulatory Medical Care Survey (NHAMCS) the following waivers:

1. In accordance with 45 CFR 46.116(d), the Board previously approved a waiver of the requirement 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 the Health Insurance Portability and Accountability Act (HIPAA) Privacy Regulation (45 CFR 164.512), the Board also previously 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 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.
    (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.