AMERICAN INSTITUTES FOR RESEARCH®

February 18, 2010

Dear Sir or Madame:

This letter provides additional information concerning the waiver of authorization (of informed consent) for the AHRQ and CDC sponsored research on use of antimicrobial agents in nursing facilities, (Project Number 02434.008). In the approval of a HIPAA waiver issued by the American Institutes for Research's IRB on February 18, 2010, the IRB determined that the waiver satisfies the three criteria specified in 45 CFR 164.512 of the Privacy Rule in whole. Below, information is provided concerning the way in which the project is meeting each of the criteria.

Criterion 1- The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:

(a) An adequate plan to protect the identifiers from improper use and disclosure;
(b) An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, and
(c) 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.

AIR is working with AHRQ and the CDC to study and standardize antibiotic use in nursing facilities. The data that will be collected during this phase of the study will only be for usability testing of the protocol/data collection from of the proposed intervention to reduce antibiotic use in these facilities. The data will not be used in any subsequent analyses. AIR will test the usability of the protocol in four nursing facilities with two patients in each of the facilities. The data will be collected from the infection logs which are minimum data sets that are required universally required by law. Depending upon the record keeping system used in the nursing facility, there might be other record systems associated with the infection log such as a separate record of contact with the resident's physician. These records are not publically available and they identify the resident and thus are Protected Health Information under HIPAA. However AIR will not abstract any of the individual identifiers as defined by HIPAA. Therefore, the identifiers are protected from improper use and disclosure because there are none.

This research is of minimal risk as it is a review of extant data that will be de-identified. The only risk is a breach of confidentiality. The record abstractors, who are licensed health professions and are employed by the Texas Quality Improvement Organization (TMF). TMF, are very experienced handling confidential health information. They routinely look at these kinds of records as part of their regular QIO activities. They will not abstract identifiers, so they will see the identifying information, but will not remove it from the records. All data collectors are trained in human subjects research and have conducted similar work in nursing homes in the past as part of their non-research work for the QIO. All data at the nursing home is already collected and available to nursing home staff. The abstractors, who are licensed health professionals, can incur serious sanctions including loss of professional licensure if confidentiality is broken.

Finally, this research involves only minimal risk because it is on a topic that is not especially sensitive. The data does not contain any information of an embarrassing nature as it does not contain information on sexual history, drug use or any illegal activities.

Criterion 2 – The research could not practicably be conducted without the waiver.

This research could not be practicably carried out without this waiver. The individuals who are studied are both physically and cognitively impaired which impedes them from providing consent. There will be no individual contact with the patients in the facility and AIR will only be collecting extant data.

Criterion 3 – The research could not practicably be conducted without access to and use of PHI.

This research, by definition requires the use of PHI. The extant data that will be collected is on the use of antibiotics in people who had an infection while living in a nursing facility. This diagnostic information obviously requires the use of PHI. This study cannot be practicably conducted without PHI.

Please let me know if you require any additional information. Thank you.

Sincerely,

Mary B. Tierney, MD, FAAP
IRB Member
FWA00003952