HIPAA Waiver of Authorization Form

Principal Investigator: Charles D. Phillips, PhD, MPH **IRB Number:** 2009-0862

Project Title: Standardizing Antibiotic Use in Long-term Care (SAUL)

Under the federal privacy rule, 'HIPAA', research use or disclosure of an individual's identifiable health information requires the individual's authorization, unless the use or disclosure is determined by the IRB to qualify for a waiver.

I. List the health information that is to be collected for the research activity, and, explain why this health information is the minimum necessary to meet the research objectives.

The only individual identifiable information used in the study will be nursing homes residents' name and medical record numbers. These data are necessary to assure that individuals who appear more than once in the data can be identified and the proper project-generated resident identifier used for information on that resident's treatment with antibiotics.

II. Identify the source of the health information (e.g., medical record etc).

Health information will be gathered from infection logs and resident medical records in participating nursing homes. However, no personal identifying data will leave the nursing home.

III. **The use or disclosure of PHI for this research activity must involve no more than minimal risk to the privacy of individuals, based on the presence of the following 3 elements:**

a. An adequate plan to protect the identifiers from improper use and disclosure. Describe this plan and indicate where PHI will be stored, and who will have access.

The focus of the data collection is to record antibiotic use in the nursing home, and a resident may have more than one infection during the study. Each infection will be considered a separate case for some analyses, but other analyses will use the resident as the unit of analysis. Thus, we need to create both infection- specific records and resident-level records that link all infections and medical records data for the same resident over the course of the study.

At the initial data collection visit, research staff will review facility infection logs in which all residents with an infection are listed by name. They will then review the medical records of the nursing home residents listed on the infection log. An otherwise meaningless study ID will be assigned to each resident listed in the infection log. The file linking the identity of the resident to the study ID number (the "linkage file") will be kept at the facility in the possession of the facility's study coordinator (usually the Director of Nursing or other person designated by the

nursing home director). The linkage file is needed so that study staff can link the infection log and medical record data for the resident at the initial data collection.

Because data will be collected at each home five times over the 9-month study period, it will also be necessary to check patients identified in the infection log at subsequent data collection visits to be sure that their data are linked to their previous data if a study ID already exists for that person. If the resident has not previously appeared on the infection log and does not have an existing study ID, study staff will assign a new study ID to that resident. This procedure will enable us to create a complete resident-level record of all study data from all data collection visits. The study ID is the only identifying information that will leave the nursing home.

In addition to the resident study ID, each infection listed on the infection log is given a project-generated infection ID number. The infection ID number will include the resident ID number to facilitate linkage of infections to residents.

The linkage file will be stored securely in the nursing home in a locked cabinet in the office of the individual designated by the home's director. It will only be consulted when the research staff members are reviewing the infection log. This will be done so that a resident with multiple infections will receive only one project-generated resident identification number. This linkage file will never leave the nursing home.

All data will be collected using computer-assisted data entry. The data collection form loaded on the data collection computers will contain the resident's project-generated number and no personal identifying information.

The research staff involved in the data collection will be experienced health professionals (nurses and therapists) who have completed the CITI training. They will sign specific confidentiality statements related to project data. In addition, they will be employees of the firm contracted to serve as Texas's Medicare Quality Improvement Organization (QIO). As a Medicare QIO, the firm and its staff members are already engaged in reviewing identifiable nursing home resident data, are aware of all issues related to the confidentiality of medical information, and have a demonstrated record of maintaining confidentiality.

b. An adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is required by law.

Research staff members will shred the linkage file in the presence of nursing home staff when the analysis files for the project are cleaned and ready for use in the analysis. The nursing home staff member will sign a form indicating that the list has been destroyed. That form will be stored by the research team, and a copy will be provided to the home.

c. Adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by law, or for other research which would be specifically approved by the IRB and would qualify for a waiver of authorization. **Principal investigator signature at the end of this document signifies assurance of compliance with this requirement.**

IV. **The research cannot practicably be carried out without the waiver.**

Explain why:

A majority of nursing home residents have some level of cognitive impairment. Gaining informed consent from them is not possible. For that smaller percentage of residents who can give consent, they often have hearing or vision problems that make the consent process difficult. In addition, those capable of consent are often hesitant to sign any type of form presented by anyone other than their trusted caregivers because of fear of exploitation.

In addition, in this study the consent process will be more intrusive on a resident's privacy than the planned data collection, which involves no contact with the resident and no transfer of personal identifying information outside the nursing home.

V. **The research could not practicably be conducted without access to, and use of, the PHI.**

Explain why:

The infection log and medical record data are PHI, because they include clinical data about identifiable residents. We are collecting no data directly from residents and will have no interaction with residents, so the infection log data are necessary to identify eligible residents and the infection log and medical record are the main data for the study.

The linkage of the study ID to the resident identity is necessary to develop variance estimates and confidence intervals for statistical tests. Standard tests require independent observations or, failing independence, some adjustment for non-independence. This requires that individuals who appear more than once in a database be identified. Lacking that information, analyses will have an increased likelihood of Type II error because of bias in the variance estimates. The only way to "flag" those who appear multiple times in the database is through some minimal use of PHI.

My signature below assures that the PHI obtained as above will not be reused or disclosed to any other person or entity, except as required by law, or for other research specifically approved by the IRB (and again, qualifying for a waiver of authorization)

Principal Investigator

Date