REQUEST WAIVER- CONSENT OR DOCUMENTATION OF CONSENT
Texas A&M University
Consent Process for Human Subjects in Research

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This form is used to request a waiver or alteration of consent as defined in 45 CFR 46.116-117. Please read the criteria below for both kinds of waivers. Only one type of waiver should be requested. For more information about waivers, read "Which Waiver do I Use?" and HSPP 300-323: Waivers or Alterations to the Consent Process or Documentation Requirements on the HSPP/IRB Website, or call 458-4067.

Project Title: STANDARDIZED USE OF ANTIBIOTICS IN LONG-TERM CARE (Phase 1)

Waiver of Consent
I certify that my research study meets '*all four*' of the following criteria:

X 45 CFR 46.116

1. The research involves no more than minimal risk to the participants;
2. The waiver or alteration will not adversely affect the rights and welfare of the participants;
3. The research could not practicably be carried out without the waiver or alteration; and
4. Whenever appropriate, the participants will be provided with additional pertinent information after participation.

OR

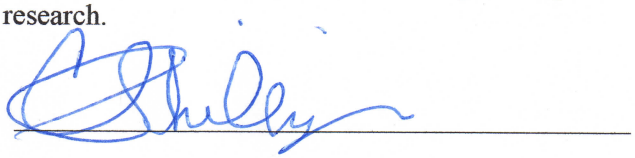
Waiver of Documentation of Consent
I certify that my research study meets '*at least one*' of the following criteria:

X 45 CFR 46.117

1. The only record linking the participant and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant will be asked whether the participant wants documentation linking the participant with the research, and the participant's wishes will govern; or

   In order to seek resident consent the researcher nurse would have to record a resident's name from the infection log, determine the current cognitive status of the resident, determine the resident's current location, and then schedule and complete a personal interview solely for the purpose of obtaining consent to review records from which no personal identifying information will be collected. Each of the steps for obtaining individual, resident consent would involve gathering individual identifying data, while the research protocol involves the collection of no personal identifying information about any resident. This waiver is sought only for Phase 1 of the project (an instrument usability test) involving four nursing homes and information on eight nursing home residents

2. That the research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context. In cases in which the documentation requirement is waived, the IRB may require the investigator to provide participants with a written statement regarding the research.

Signature of Principal Investigator: 

Date: **12/02/2009**

Typed/Printed Name: **Charles D. Phillips**