

Texas A&M University
Amendment Application For the Use of
Human Subjects in Research

HSPP Office Use Only

Instructions

1. Complete Form

Form must be typed, single-sided and free of typographical/grammatical errors.

2. Attach Documents to Application

- Any modified document or protocol, i.e. survey instrument, interview questions, consent form, etc.
- Please note that you do not need to submit the original versions or the Initial Review Application.
- If you are adding a new investigator to an existing project, please submit a Conflict of Interest Statement and human subjects' training certificate for him or her and add contact information to the consent form, if appropriate.

3. Submit Application

Submit this application with signatures and any additional documentation to:

On Campus: HSPP/IRB, MS 1186

In Person: General Services Complex, 750 Agronomy Rd, Suite 3501

Off Campus: HSPP/IRB, 750 Agronomy Rd, Suite 3501, College Station, Texas 77843

If you have any questions or need assistance completing this application, please call
(979)458-4067 or email irb@tamu.edu

Information

IRB PROTOCOL #: 2009-0862

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

Principal Investigator Name: **Charles Phillips**

Faculty Staff Graduate Student Undergraduate Student

Department: **Health Policy** College: **SRPH** Mail Stop: **1266**

Phone: **458-0080** Email: **phillipscd@srph.tamhsc.edu** Fax: **458-0656**

Are any amendments to the grant proposal or contract attached? Yes No N/A

Description of Proposed Changes

1. What is to be changed? This is a request for approval to move to the Small-Scale Trial phase of the project. Data collection procedures do not change from those approved by the IRB for the Usability Test. These data collection procedures will be used in four nursing homes for four months. Also, the homes will be implementing a new strategy for providing information to physicians about possible infections, which is the project's intervention.

2. Why is this change needed? Initiation of a new project phase

3. Is this change to *replace* an original procedure(s)? Yes No
If Yes, describe which documents/processes are no longer to be used: _____

4. Is this change an *addition* to original procedure(s)? Yes No

Nursing home staff will be trained in the use of the physician communication form, which they will use for three months. Material on the new procedure will be provided to physicians caring for residents in these four homes. All data collection remains record review in the homes, and no personally identifying information is collected. No consent forms are used, since the medical records are property of the nursing home. Written permission to review records in the home will be provided by the nursing home administrator. Information will be collected from approximately 400 medical records. Homes will also provide aggregate monthly data on deaths, discharges to the hospitals, emergency room visits, and occupancy.

5. Does Consent Form or Information Sheet need to be edited to reflect these changes? Yes No
If Yes, please attach the revised Consent Document.

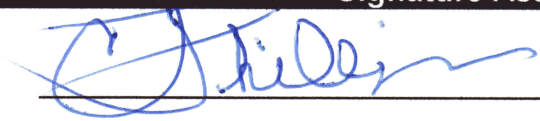
As indicated, no consent form is used. However, we have attached all information prepared for the nursing home and for the individuals preparing to do data collection in the home. These include copies of the:

- Communication and Order Form
- Physician's information packet
- SAUL- one page information sheet
- Talking points for project staff meeting with nursing home supervisory personnel
- Loeb criteria visualization – a graphic presentation of the information on the Communication and Order Form
- SAUL-phase 2- memorandum of understanding for nursing homes
- SAUL study letter draft for nursing home physicians
- SAUL study PD – screen shots for electronic data collection

6. Has the level of risk to the participant increased? Yes No

Signature Assurance

Signature of PI: _____



Typed Name: **Charles D. Phillips**

Date: _____

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Undergraduate and graduate students must have faculty/research advisor's signature.

Signature of Faculty Advisor: _____

Typed Name: _____

Date: _____