REVIEW OF SAFEGUARDS FOR HUMAN SUBJECTS

American Institutes for Research
1000 Thomas Jefferson Street, NW
Washington, DC 20007

Institutional Review Board
IRB00000436

Project number: 02434.008
Project Director/Proposal Author: Steven Garfinkel
Project/Proposal title: **SAUL (Small Scale Trial)**

1. Type of review:

(Check one)
- ☒ Expedited review
- ☐ Full IRB review

(Check one)
- ☐ Initial review
- ☐ Scheduled re-review (e.g., annual)
- ☒ Requested re-review (e.g., new data collection component, research plan change)

2. Review determination:

After reviewing the above *project amendment* the Institutional Review Board (or member signing below) has determined the following:

☐ Determination of Exemption: the project is exempt from further IRB review because it does not constitute research or because it does not involve human subjects.

☐ Provisional Approval: the submitted *insert "project/study/proposal or other descriptive"* is approved pending development of the research plan (45CFR46.118), which must be reviewed before enrollment of subjects or collection of data can begin. Proposed date of review: __

☐ Conditional Approval: data collection of *insert "project/study/proposal or other descriptive"* can proceed after meeting the following conditions:

☒ **Approval: approval of *project amendment* is granted and data collection can proceed. In keeping with our Federalwide Assurance mandate the IRB must conduct reviews at least annually for each project. This project will be reviewed again on *8/28/10*.**

☐ Approval Denied: approval of *insert "project/study/proposal or other descriptive"* is denied and data collection may not proceed for the following reasons:

3. Consent Procedures

The Institutional Review Board has determined that consent procedures:

☐ are not applicable to the project.

☐ must be reviewed on .

☒ **are approved as submitted.**

☐ are approved under the following conditions:

☐ are not approved for the following reasons:

4. Individually Identifiable Information Safeguards

The Institutional Review Board has determined that the safeguards planned for individually identifiable information:

☐ are not applicable to the project.

☐ must be reviewed on .

☒ **are approved as submitted.**

☐ are approved under the following conditions:

☐ are not approved for the following reasons:

5. Comments

On the basis of this review, the IRB has determined that the study, as described in the materials you submitted, is approved. The risks to the participants are minimized. The subjects are nursing home residents. There are no physical or emotional risks since it is a review of health records such as infection logs. The content of the study is not of a sensitive or personal nature. It is a study of the use of antibiotics in nursing homes. The procedures for protecting the confidentiality of the collected data are adequate.

The data is collectd by the Texas quality improvement organization (QIO): TMF Health Quality Institute in partnership with Texas A&M. The information will be abstracted by TMF and will contain no personal identifiers. The data will be abstracted by licensed health care professionals who are experienced abstractors. The data that will be abstracted will not contain any of the 18 identifiers specified by HIPAA as protected health information.

In addition, a HIPAA waiver of authorization of consent was previously granted on February 18, 2010 and contiues to stand. The project staff has reqested both a waiver of consent and a waiver of documentation of consent. The waiver of informed consent is granted because it involves no more than minimal risk to the subjects because of the reasons discussed in this paragraph. The waiver will no adversely affect the rights or welfare of the subjects. The research can not be practicably be carried out without the waiver. The staff collecting the

data would have to determine the current cognitive status of the subject, determine their location and schedule a personal interview. This would result in their gathering personal identifying information which is not appropriate for this study. There is also no need to provide the subject with additional information after the completion of the study. A waiver of documentation of consent is also granted. The only record linking the subject with the research would be the consent document and would result in a breach of confidentiality. In addition the research presents no more than minimal harm for which written consent is required outside of the research context.

6. IRB Signature(s):

6/25/10
Date

Mary B. Tierney, MD
IRB Representative

Please keep in mind that any material changes made to the study or the study procedures require advance IRB review and approval.