REVIEW OF SAFEGUARDS FOR HUMAN SUBJECTS

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

Institutional Review Board
IRB00000436

Project number: 02434.007
Project Director/Proposal Author: Kristin Carman
Project/Proposal title: **Patient and Family Engagement (Task 7)**

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 *7/16/11*.**

☐ 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 project amendment, as described in the materials you submitted, is approved. The risks to the participants are minimized. The current participants are over the age of 25 years. There are no questions of a personal or sensitive nature. The staff of the project is requesting a waiver of documentation of informed consent for the semi-structured interviews and the observation of the health care providers. The waiver is granted because the research presents no more than minimal risk to participants for which consent is required outside of the research context. In addition, patient surveys will be handed to them as they are leaving the hospital. Since the data are to be collected by means of a mailed survey form, return of a completed survey booklet can be interpreted as indicating consent to participate. Thus, the procedures for obtaining informed consent are appropriate. The procedures for protecting the confidentiality of the collected data are adequate as well.

6. IRB Signature(s):

4/12/11
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.