



An Employee-Owned
Research Corporation

Memo

Date: March 4th, 2009

To: Debra Rog, Project Director

From: Kerry Levin, Chair Westat IRB *Kerry Levin*

Subject: **Exemption of CTSA Process Evaluation, Project 8668
FWA 5551**

As Chair of the Westat Institutional Review Board (IRB), I have reviewed the materials submitted for the following: **CTSA Process Evaluation, Project 8668**. Pursuant to 45 CFR pt. 46, the IRB reviews all studies involving research on human subjects. This project is funded by the National Center for Research Resources.

Westat will conduct an evaluation for the Clinical and Translational Science Awards program. This process evaluation will focus on the implementation of the National CTSA programs and the national Consortium. Westat will develop the evaluation framework and data collection instruments as well as develop and implement the protocol for data collection.

Per 45 CFR 46 101 (b) (5) and based on the information provided, this project is exempt from IRB review because the research is determined to be minimal risk and is designed to be a research or demonstration project (program evaluation) that studies or evaluates a service program.

If activities change, please contact the IRB Office to ensure that the status is accurately reflected in our records. You are only required to submit the study for a continuing review on or before March 4, 2010 if activities change for this project. In the interim, you are responsible for notifying the IRB Office as soon as possible if there are any injuries to the subjects, problems with the study, or changes to the study design that relate to human subjects.

cc: Institutional Review Board
Ann Bennett