Westat | An Employee-Owned Research Corporation

Memo

Date: December 13, 2013

To: Lois Olinger, Project Director

From: Kerry Levin, Chair Westat IRB

Subject: **Expedited Approval of CMS Wellness Evaluation, Project 8926.04**
FWA 00005551

As Chair of the Westat Institutional Review Board (IRB), I reviewed the materials submitted for the following: **CMS Wellness Evaluation, Project 8926.04.** The Westat IRB reviews all studies involving research on human subjects. This study is funded by the Center for Medicare and Medicaid Services.

Westat is a subcontractor to Acumen, LLC for this prospective evaluation of wellness programs.

Westat's tasks include the following research activities in-person, mail and by telephone:

- National Readiness Survey;
- Partnerships with Wellness Programs;
- Wellness Program Participant Survey;
- Disenrollee Survey;
- Survey Cognitive Testing; and
- Qualitative Study of Program Operations and Costs.

IRB regulations permit expedited review of certain activities involving minimal risk [45 CFR pt. 46.110]. This study can be considered minimal risk and is approved under expedited authority. Per 45 CFR 46 117, a waiver of documentation of informed consent is also approved as the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally conducted outside of the research context.

As the Project Director you are responsible for the following:

- **Inform the IRB when you have obtained information regarding wellness program partners involved in this project.**
- You are required to submit this study for a continuing review on or before December 13, 2014.
- In the interim, notify the IRB Office as soon as possible if there are any injuries to subjects as well as problems or changes with the study that relate to human subjects.

cc: Institutional Review Board
Nancy Atkinson