Attachment 7

IRB Approvals

Westat
An Employee-Owned
Research Corporation

1600 Research Boulevard
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fax: 301-294-2040
www.westat.com

Date: January 24, 2014

To: Jocelyn Marrow, Project Director

From: Kerry Levin, IRB Administrator, Westat IRB Kerry Levin

Subject: **Exemption of Study of the AREA PROGRAM EVALUATION, Project 6221 FWA 00005551**

As Chair of the Westat Institutional Review Board (IRB), I reviewed the materials submitted for the following: **AREA PROGRAM EVALUATION, Project 6221.** The Westat IRB reviews all studies involving research on human subjects. This study is sponsored by the National Institutes of Health.

Westat will be extracting and manipulating data from the IMPAC II system, a database of grants funded by the NIH since the 1990s. Westat will be examining the research output of PIs receiving the grants, award amounts, and students work hours supported with the grants.

Per [45 CFR 46.101(b5)] and a letter received (on January 23, 2014) from Sandeep Somaiya, Contract Program Manager/Director, NET ESolutions Corporation; this research involves a program evaluation and therefore is exempt from IRB review.

The Project Director is required to notify the Board only if there are changes to the protocol or procedures regarding this project. In addition, notify the IRB Office as soon as possible if there are any injuries to the subjects or problems with the study that relate to human subjects.

cc: Institutional Review Board
Nancy Weinfield

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AMENDMENT REVIEW FORM

(TO ADD OR CHANGE PREVIOUSLY APPROVED RESEARCH)

All changes or new activities for previously approved studies require submission, review, and approval of an Amendment Review Form. Please complete and upload this form to your project's document library on IRBTRAC along with all other necessary materials to be reviewed. Once the request has been reviewed, you will be contacted. If this change or new activity requires a full Board review, those meetings occur on the second Tuesday of every month. To check the date of meetings, please see the meeting schedule under IRB in WesInfo. Thank you for your cooperation.

1. **Today's Date:** 08 / 28 / 2014

Date of Original Approval: 02 / 06 / 2014

Project Name: AREA Program Evaluation

Westat Project Number: 6221.00.00

Agency Grant or Contract Number: NETE-WESTAT-OEP-2014

Project Director: Jocelyn Marrow **Ext.** 5887

Unit Ops Number/Study Area: 1121.72

Area IRB Representative: Alicia Sutherland **Ext.** 8860

2. **Indicate the type of addition or change being requested to a previously approved study.**
(SELECT ALL THAT APPLY.)

- ☐ Name(s) of investigators
- ☐ Project number
- ☐ Introduction of a new IRB or request for Westat to serve as the IRB
- ☐ Study design, survey questionnaire, or procedure(s)
- ☐ Informed consent process, consent form(s), parent permission(s), or assent form(s)
- ☒ Recruitment materials or strategies
- ☐ Incentives
- ☒ Survey instruments
- ☐ Number or type of populations studied
- ☒ Review of final instrument such as interview questions or data collection sites for a previously approved study
- ☐ Mode of administration of instruments in your study (e.g., from mail or telephone to web or Internet access)
- ☐ Data access rights
- ☐ Any other change in protocol that affects treatment of human subjects:
(PLEASE SPECIFY)

3. **Please provide a brief summary of your change or addition to previously approved research.**

Changes were made to surveys to clarify questions per the results of cognitive interviews. A semi-structured interview protocol has been added.

4. **How does each change or addition affect the risks to participants in your study?** ***(SELECT ONLY ONE.)***

a. ☐ **No change**

b. ☒ N/A – no risks

c. ☐ Decreases the risk ***(SPECIFY)***:

d. ☐ Increases the risk ***(SPECIFY)***:

e. ☐ Adds a new risk ***(SPECIFY)***:

FOR HARD-COPY SUBMISSION, PLEASE SIGN HERE:

A signature is not required when you return this form electronically; however, please fill in the date of completion.

The information provided in this request form is complete and correct.

Project Director/ Principal Investigator: _____ **Date:** 08 / 28/ 2014

Please attach:

- **One document that clearly identifies (through track changes, highlights, or italics) the revision in the previously approved submission.**
- **Another document labeled "corrected version."**

If you have any questions, feel free to contact Sharon Zack, the IRB Administrator, at x8828.

IRB Administration Use Only

Expedited review and approval for the modification(s) on this form:

Kerry Levin

9/4/14

IRB Chair / Associate Chair / Designee

IRB Office Only

☒ APPROVED – NEXT CONTINUING REVIEW DATE BEFORE: 05 / 08/ 2015

☐ CONDITIONAL APPROVAL (PLEASE SEE ATTACHED LETTER)

☐ DID NOT QUALIFY FOR EXPEDITED REVIEW