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DATE: February 3, 2016

TO: Roline Milfort

FROM: Kerry Levin
Chair, Institutional Review Board

SUBJECT: IRB Continuing Review and Approval
Project Name: CACFP IMPROPER PAYMENTS
Project: 6278.01
FWA 00005551

On February 2, 2016, the Westat IRB Continuing Review Committee conducted its continuing review of the following: CACFP IMPROPER PAYMENTS, Project # 6278.01. Pursuant to 45 CFR pt 46.109(e), continuing review of research studies occurs at intervals appropriate to the degree of risk but not less frequently than once a year.

In accordance with 45 CFR pt 46, the Board approved the continuation of this study. The next continuing review will be due on or before February 2, 2017. In the interim, you are responsible for notifying the Institutional Review Board (IRB) Office as soon as possible if there are any injuries to the subjects, problems with the study, or changes to study design that relate to human subjects.

cc: Institutional Review Board - Sharon Zack

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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 / 21 / 2015	
Date of Original Approval:	03 / 16 / 2015	
Project Name:	Erroneous Payments in Child Care Center Study or EPICCS (Contract Name: CACFP Improper Payments Study)	
Westat Project Number:	6278.01.00	
Agency Grant or Contract Number:	AG3198C140015	
Project Director:	Roline Milfort	**Ext.** 8229
Unit Ops Number/Study Area:	21.72.1	
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)

Description of the proposed approach for main study's contact of parents and guardians for completion of a household survey. Preparation for the interview and incentive plans are revised.

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

Previous approvals were obtained for pretest activities only. This submission provides details for the main study.

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 / 21/ 2015

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:

Sharon Zack
2015-09-18 12:26 PM
I agree to the terms defined by the placement of my signatur

IRB Chair / Associate Chair / Designee

IRB Office Only

☒ **APPROVED** – NEXT CONTINUING REVIEW DATE BEFORE: 03 / 17/ 2016

☐ **CONDITIONAL APPROVAL** (PLEASE SEE ATTACHED LETTER)

☐ **DID NOT QUALIFY FOR EXPEDITED REVIEW**