

APPENDIX G2. WESTAT IRB APPROVAL LETTER



An Employee Owned
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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 submit this form to irb@westat.com and attach all 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:	04 / 18 / 2012	
Date of Original Approval:	01 / 00 / 2012	
Project Name:	FRMS MKT CLIENT SURVEY Farmers Market Client Survey (FMCS)	
Westat Project Number:	8876.02.00	
Agency Grant or Contract Number:	AG-3198-B-10-0029	
Project Director:	Mustafa Karakus	Ext. 2874
Unit Ops Number/Study Area:	1.21.76-Health Studies/NCS	
Area IRB Representative:	Karen Della Torre	Ext. 2832

2. Indicate the type of addition or change being requested to a previously approved study.

(SELECT ALL THAT APPLY.)

- | | |
|---|---|
| <input type="checkbox"/> Name(s) of investigators | <input checked="" type="checkbox"/> Review of final instrument such as interview questions or data collection sites for a previously approved study |
| <input type="checkbox"/> Project number | <input checked="" type="checkbox"/> Mode of administration of instruments in your study (e.g., from mail or telephone to web or Internet access) |
| <input type="checkbox"/> Introduction of a new IRB or request for Westat to serve as the IRB | <input type="checkbox"/> Data access rights |
| <input checked="" type="checkbox"/> Study design, survey questionnaire, or procedure(s) | <input type="checkbox"/> Any other change in protocol that affects treatment of human subjects: |
| <input type="checkbox"/> Informed consent process, consent form(s), parent permission(s), or assent form(s) | (PLEASE SPECIFY) |
| <input checked="" type="checkbox"/> Recruitment materials or strategies | <div style="border: 1px solid black; height: 40px; width: 100%;"></div> |
| <input type="checkbox"/> Incentives | |
| <input checked="" type="checkbox"/> Survey instruments | |
| <input type="checkbox"/> Number or type of populations studied | |

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Amendment Review Form

Submit materials by email: IRB@westat.com

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

This is the addition of new materials. The original approval was for cognitive testing of the questionnaire. This amendment is for the full study and includes letters, questionnaires, refusal conversion text, and focus group materials that were not seen previously.

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.

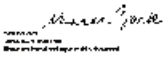
Project Director/
Principal Investigator:

Date: 04 / 18/ 2012

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:  <small>SHARON ZACK IRB ADMINISTRATOR WESTAT, INC.</small>
_____ IRB Chair / Associate Chair / Designee
IRB Office Only <input checked="" type="checkbox"/> APPROVED – NEXT CONTINUING REVIEW DATE: 01 / 00/ 2013 <input type="checkbox"/> CONDITIONAL APPROVAL (PLEASE SEE ATTACHED LETTER) <input type="checkbox"/> DID NOT QUALIFY FOR EXPEDITED REVIEW