

APPENDIX BB  
 AGE 3 EXTENSION WIC INFANT AND TODDLER FEEDING PRACTICES STUDY -II  
 IRB APPROVAL LETTER



An Employee-Owned  
 Research Corporation

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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.

<b>1. Today's Date:</b>	10 / 29 / 2014	
<b>Date of Original Approval:</b>	02 / 24 / 2012	
<b>Project Name:</b>	WIC Infant-Toddler Feeding Practices - II (Feeding My Baby - A National WIC Study)	
<b>Westat Project Number:</b>	8967.01.00	
<b>Agency Grant or Contract</b>	GS-23F-8144H	
<b>Project Director:</b>	Suzanne McNutt	<b>Ext.</b> 3554
<b>Unit Ops Number/Study</b>	1.21.72/Cancer Studies	
<b>Area IRB Representative:</b>	Nancy Weinfield	<b>Ext.</b> 2480

**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<br><input type="checkbox"/> Project number<br><input type="checkbox"/> Introduction of a new IRB or request for Westat to serve as the IRB<br><input checked="" type="checkbox"/> Study design, survey questionnaire, or procedure(s)<br><input checked="" type="checkbox"/> Informed consent process, consent form(s), parent permission(s), or assent form(s)<br><input type="checkbox"/> Recruitment materials or strategies<br><input checked="" type="checkbox"/> Incentives<br><input checked="" type="checkbox"/> Survey instruments<br><input type="checkbox"/> Number or type of populations studied | <input type="checkbox"/> Review of final instrument such as interview questions or data collection sites for a previously approved study<br><input type="checkbox"/> Mode of administration of instruments in your study (e.g., from mail or telephone to web or Internet access)<br><input type="checkbox"/> Data access rights<br><input checked="" type="checkbox"/> Any other change in protocol that affects treatment of human subjects:<br>(PLEASE SPECIFY)<br><div style="border: 1px solid black; padding: 5px; margin-top: 5px;">                     flyers announcing study extension<br/>                     advance letters for interviews and activities<br/>                     HIPAA release form<br/>                     contact update forms                 </div> |
|---|---|

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

FNS has asked us to extend the study another year to child age 36 months. We are revising the 24-month interview to remove one question and add contact info requests since it is no longer the last interview. We are adding new consent, two caregiver interviews, requests to get child measured and weighed, more WIC administrative data at 36 months, and a new HIPAA authorization, as well as an announcement flier, three contact update requests, and advance letters for the interviews.

**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:**

10 / 29 / 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*

11/13/14

\_\_\_\_\_  
IRB Chair / Associate Chair / Designee

**IRB Office Only**

- APPROVED** – NEXT CONTINUING REVIEW DATE BEFORE: 02 / 24/ 2015
- CONDITIONAL APPROVAL** (PLEASE SEE ATTACHED LETTER)
- DID NOT QUALIFY FOR EXPEDITED REVIEW**