Westat®
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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:**	01 / 16 / 2013	
Date of Original Approval:	10 / 10 / 2012	
Project Name:	Study to Explore Distribution, Reach, and Influence of Educational Children's Book Amazing Me. It's Busy Being 3! In Pediatric Office Settings	
Westat Project Number:	8417.10.	
Agency Grant or Contract Number:	CDC 200200720015	
Project Director:	Erika Reed-Gross	**Ext.** 455-4897
Unit Ops Number/Study Area:	1121-76	
Area IRB Representative:	Sharon Zack	**Ext.** 8828

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.

An additional task/phase has been approved and thus added to this project. This new task (Task 1) will involve focus groups with parents, a parent web survey, and interivews with clinic administrators. Study participants will be recruited from 6 pediatric clinics recruited to particiapte in the 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: 01 / 16/ 2013

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
Sharon Zack
2013-01-18 10:38 AM
I have reviewed and approve this document

IRB Chair / Associate Chair / Designee

IRB Office Only

☒ **APPROVED** – NEXT CONTINUING REVIEW DATE: 10 / 00/ 2013

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

☐ **DID NOT QUALIFY FOR EXPEDITED REVIEW**