

Memo

Date: May 13, 2013

To: Sunitha Mathew, Project Director

From: Kerry Levin, Chair Westat IRB *Kerry Levin*

Subject: **Amendment Approval for NCS Methodological Planning & Development: Bailey Child Development Study, Project 8868**
FWA: 00005551

As Chair of the Westat Institutional Review Board (IRB), I reviewed the materials submitted for the following: **NCS Methodological Planning & Development: Bailey Child Development Study, Project 8868**. The Westat IRB reviews all studies involving research on human subjects. This project was last reviewed in March 2013.

This request was to approve the following modifications:

- Revised the Project Summary to provide more details and specificity.
- Revised study screener, recruitment flyer, recruitment cover letter and the consent form to add the NCS logo/space for NCS logo, and the OMB approval number and expiration date.
- Study name change from the "The Bayley Study", or the "Short Bayley Study" to "The Bayley Child Development Study".

The regulations (45 CFR 46) permit expedited review of minor changes to previously approved activities. I am therefore approving the modifications under expedited authority. This study can be considered minimal risk and is approved under expedited authority.

As the Project Director you are responsible for the following:

- You are required to submit this study for a continuing review on or before January 1, 2014.
- In the interim, notify the IRB Office as soon as possible if there are any injuries to subjects as well as problems or changes with the study that relate to human subjects.

cc: Institutional Review Board
Karen Della Torre

Memo

Date: March 4, 2013

To: Sunitha Mathew, Project Director

From: Kerry Levin, Chair Westat IRB 

Subject: **Amendment Approval of NCS Methodological Planning & Development,
Project 8868
FWA 00005551**

As Chair of the Westat Institutional Review Board (IRB), I reviewed the materials submitted for the following: **NCS Methodological Planning & Development, Project 8868**. The Westat IRB reviews all studies involving research on human subjects. This project was last reviewed in February 2013.

This request was to approve a brief, cost-effective and psychometrically sound direct assessment of early childhood cognitive, language, and motor development useful for the NCS at ages 6-, 12-, 18-, 24-, and 36-months. This work will take place in a series of stages, with each subsequent stage dependent on the success of the previous stage.

The regulations (45 CFR 46) permit expedited review of minor changes to previously approved activities. I am therefore approving the modifications under expedited authority. This study can be considered minimal risk and is approved under expedited authority.

As the Project Director you are responsible for the following:

- You are required to submit this study for a continuing review on or before January 1, 2014.
- In the interim, notify the IRB Office as soon as possible if there are any injuries to subjects as well as problems or changes with the study that relate to human subjects.

cc: Institutional Review Board
Karen Della Torre