OMB #: 0925-XXXX
EXPIRATION DATE: XX/XX/XXXX

Westat | An Employee-Owned Research Corporation

Memo

Date: April 11, 2011

To: Carol Andreassen, Project Director

From: Kerry Levin, Chair Westat IRB Kerry Levin

Subject: **Initial Approval of BAYLEY-3, Project 8450.34**
FWA 05551

As Chair of the Westat Institutional Review Board (IRB), I reviewed the materials submitted for the following: **BAYLEY-3, Project 8450.34.** The Westat IRB reviews all studies involving research on human subjects. This project is sponsored by University of Texas Health Science Center at San Antonio (UTHSCSA). Westat is subcontractor to UTHSCSA.

The goal of the study is to develop age-specific short forms of the Bayley Scales of Infant and Toddler Development-Third Edition ("Bayley-3"), a standardized assessment of young children's cognitive, language and motor development.

Westat will recruit 300 young children (and their parents) between the ages of about 4 months and 44 months to participate. Exclusion criteria include children with medical diagnoses, children with a developmental delay, or children from households in which English is not the primary language spoken in the home. Documented informed consent will be obtained from parents or legally authorized representatives (LARs) for their child's participation.

Westat will administer the 35-70 minute Bayley-3 forms.

Data will be recorded on hard copy Bayley forms. Individual child names will not be entered on the Bayley forms; data will not use identifiers. The results of the research will be presented by collecting the information of all study participants.

IRB regulations permit expedited review of certain activities involving minimal risk [45 CFR pt. 46.110 (b) (1), 404]. This study can be considered minimal risk and is approved under expedited authority. Per 45 CFR 46 408 b, a waiver to accept permission of one parent is sufficient.

As the Project Director you are responsible for the following:

- You are required to submit this study for a continuing review on or before April 11, 2012.
- 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
Adriana Brigatti