

## Memo

**Date:** April 4, 2014

**To:** Erika Bonilla, Project Director

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

**Subject:** **Expedited Approval of LEARN THE SIGNS ACT EARLY, Project Number 8417.15  
FWA 00005551**

As Chair of the Westat Institutional Review Board (IRB), I reviewed the materials submitted for the following: **LEARN THE SIGNS ACT EARLY, Project Number 8417.15**. The Westat IRB reviews all studies involving research on human subjects. This study is funded by the Centers for Disease Control and Prevention.

The purpose of this study is to refine development of “Learn the Signs, Act Early”, a campaign for low income parents to identify and help children with developmental disabilities at the earliest age possible. Westat will recruit 6 pediatric clinics in Georgia and Maryland in order to conduct the study.

Westat will conduct focus groups with parents and in-depth interviews with providers or other members of the health care team in order to provide recommendations to existing LTSAE concepts and messages.

Further research with campaign prototypes will be evaluated during the following activities:

- Focus groups and intercept interviews in clinic waiting rooms
- In-depth interviews with providers

IRB regulations permit expedited review of certain activities involving minimal risk [45 CFR pt. 46.110]. This study can be considered minimal risk and is approved under expedited authority. Per [45 CFR 46 117(c)], a waiver of documentation of informed consent is also approved as the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

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 4, 2015.
- 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