ATTACHMENT 6

IRB Findings and Approval

Westat | An Employee-Owned Research Corporation

Memo

Date: February 10, 2012

To: Simani Price, Project Director

From: Kerry Levin, Chair Westat IRB Kerry Levin

Subject: **Expedited Approval of CMV Communications, Project 8417.07**
FWA 00005551

As Chair of the Westat Institutional Review Board (IRB), I reviewed the materials submitted for the following: **of CMV Communications, Project 8417.07.** The Westat IRB reviews all studies involving research on human subjects. Centers for Disease Control and Prevention funds this study.

The goal of this research will be to inform communication strategies to prevent congenital cytomegalovirus (CMV) infections. Data will be collected in two phases. Phase I consists of 8 exploratory focus groups in order to gain an understanding of audiences' knowledge, attitudes, and beliefs about CMV, their perceptions about personal risk and prevention behaviors, and their communication preferences. Phase II will include a web survey to test the effectiveness of CDC CMV communication interventions and recommended guidelines for preventing congenital CMV with the target audiences. The target audiences for this research will include Caucasian and African-American pregnant or intending to get pregnant mothers who also have a child age 5 years or younger.

Per 45 CFR 46, IRB regulations permit expedited review of certain activities involving minimal risk [45 CFR pt. 46.110 (b) 1. This study can be considered minimal risk and is approved under expedited authority. Per 45 CFR 46 117 (c) 2, a waiver of documentation of informed consent is also approved to conduct the web survey as the study is minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

Please identify the amount of incentives provided to focus group participants when that information is confirmed.

As the Project Director you are responsible for the following:

- You are required to submit this study for a continuing review on or before February 10, 2013.
- 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

Westat | An Employee-Owned Research Corporation

Memo

Date: May 7, 2012

To: Simani Price, Project Director

From: Kerry Levin, Chair Westat IRB

Subject: **Initial Approval of CMV Communications, Project 8417.07- ADDENDUM FWA 00005551**

As Chair of the Westat Institutional Review Board (IRB), I reviewed the materials submitted for the following: **CMV Communications, Project 8417.07.** The Westat IRB reviews all studies involving research on human subjects. Centers for Disease control and Prevention fund this project.

Per initial IRB approval (2/10/12), you were requested to provide information on the amount of incentives used for the focus groups. You have now met this request.

As the Project Director you are responsible for the following:

- You are required to submit this study for a continuing review on or before February 10, 2013.
- 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