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Memo

Date: April 29, 2009

To: Wendy Hicks, Project Director

From: Kerry Levin, IRB Chair

Kerry Levin

Subject: NCS IVR and Web Based Applications- Cognitive Testing Project 8208.01.03.04

FWA 5551

As Chair of the Westat Institutional Review Board (IRB), I have reviewed the materials submitted for the following: **NCS IVR and Web Based Applications- Cognitive Testing, Project 8208. 01.03.04.** The IRB reviews all studies involving research on human subjects. This study is funded by National Institute of Child Health and Human Development (NICHD). This project was reviewed on June 2008 for previous research conducted.

This amendment includes a second stage of testing with a recruited panel of approximately 200 female respondents. It begins with the in-person administration of the NCS Pilot pregnancy screener and then follows-up with three pregnancy monitoring contacts at 6 week or 12 week intervals. The pregnancy monitoring contacts will be done via an IVR data collection application, or a Web or Texting data collection application. About half the respondents will participate via IVR, and the other half will participate via Web or text depending on which of those modes the respondent reports as using the most frequently.

All panel participants will receive up to three follow-up contacts. Half the respondents will be scheduled for follow-up contacts on a 6 week cycle, and the other half will receive follow-up contacts on a 12 week cycle. Women who don’t respond in their initial assigned mode within a certain period of time will be contacted at the next follow-up in a different mode.

Additionally, 50 women who decide not to complete all 3 follow-up contacts will be called to complete a telephone debriefing interview. Thirty additional women who completed all three contacts will also be called for a short telephone debriefing interview to collect some

qualitative information about their experience with the data collection applications.

A professional recruiting agency will recruit a panel of approximately 200 women between 18 and 49 years of age. Since this stage of testing starts with a personal visit interview to administer the pregnancy screener, recruitment will be local.

As part of the recruiting questionnaire and protocol, participants will be informed about the sensitivity questions about pregnancy and sexual activity. Women who decide to participate will receive $50 compensation for their participation and time. At the end of the pregnancy screener interview, women will be asked to complete a short follow up interview in their assigned mode (IVR, Web or text) at home. For those women from the texting group, the interviewer will also ask if he or she can have their permission to text them.

All three applications also include an additional module that will be asked at the second follow-up contact only; including:

1. Verifying that she still lives at the same address where she lived at the time of the pregnancy screener;
2. Determining whether she plans on moving in the next 2 months, and;
3. Determining whether anyone has moved into or out of her home since the date of the pregnancy screener

The debriefing interview with the 50 women who completed the follow-ups will also ask if they remember these additional questions and if so, what they thought the purpose was for asking these questions.

The specifications for the applications reflect the same content as the NCS pregnancy screener previously approved by the Westat IRB. However, language has been modified to fit the self-administered setting. None of the modifications result in any substantive changes to content.

The regulations (45 CFR 46) permit expedited review of minor changes in previously approved activities. I am therefore approving the modifications under expedited authority.

If activities change, please contact the IRB Office to ensure that the status is accurately reflected in our records. The Project Director is required to submit the study for a continuing review on or before June 5, 2009. In the interim, you are responsible for notifying the Office of Research Administration as soon as possible if there are any injuries to the subjects, problems with the study, or changes to the study design that relate to human subjects.

cc: Institutional Review Board
Paul Hurwitz