



Date: November 12, 2013

TO: Office of Management and Budget (OMB)

Through: Seleda Perryman, Report Clearance Officer, NIH
Vivian Horovitch-Kelley, PRA OMB Clearance Liaison, NCI

FROM: Linda Nebeling, Ph.D., MPH, RD, FADA
Health Behaviors Research Branch, Division of Cancer Control & Population
Sciences, National Cancer Institute (NCI)/NIH

SUBJECT: Passback Questions and Responses for "Family Life, Activity, Sun, Health, and
Eating (FLASHE) Study"

Answers to OMB's questions about additional details regarding whether or not doubling the incentive (i.e., \$20 versus \$40) will have an impact on whether the device monitor is returned are below.

Question: What are the outcomes that will be compared? Is it only response rate?

Response: We plan to compare teen assent rates, response/return rates, as well as compliance rates with the protocol. Research questions and outcomes include:

- Does the incentive amount offered during the informed consent process affect the rate of assent by adolescents invited to participate in the motion study?
- Does the incentive amount affect the rate of return of the device?
- Does the incentive amount affect the speed of device return after the wear period?
- Does the incentive amount affect how many days the respondent wears the device?

Question: Does the monitor allow you to determine which days the participant used the monitor?

Response: The monitor will show which days the device was worn. It will also show if a device was worn for only a partial day.

Question: Will you be comparing overall activity levels? etc. Also, how will the program determine success? How big a change in each outcome?

Response: We will be comparing the \$20 to the \$40 incentives with respect to the research questions listed above pertaining to assent rate, return, and protocol compliance rates. We expect to have large enough sample sizes to identify statistical differences (95% confidence interval) between the groups for each research question to infer if incentive structure affects assent, return, or compliance rates. However, we do not expect the overall physical activity level of participants to be different between incentive-groups since incentive is not based on the amount of physical activity.