ATTACHMENT E:

IRB APPROVALS

ATTACHMENT E - 1:

APPROVAL LETTER FROM THE NCI SPECIAL STUDIES INSTITUTIONAL REVIEW BOARD

Department of Health & Human Services

Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

iRIS Reference Number ***327123***

Type of Action: Submission Response for Initial Review Submission Form
Project Number: P131259

05/30/2013

TO: Linda Nebeling
NCI - Division of Cancer Control and Population Sciences

FROM: Chairperson, Special Studies Institutional Review Board, NCI

SUBJECT: Action on Clinical Research Protocol

The Initial Review of your protocol and consent document, "Family Life, Activity, Sun, Health and Eating Study," was reviewed by the National Cancer Institute Special Studies Institutional Review Board (NCI-SSIRB) by full board review on 04/15/2013.

The IRB has taken the following action:

X	Approved as written. Forwarded to the CC OPS for administrative processing.
	Approved with stipulations pending re-review by SSIRB Chair. See review.
	Approved with stipulations pending re-review by a subcommittee of the Board. See review.
	Deferred pending response to stipulations and re-review by the full SSIRB. See review.
	Disapproved. See review.

ATTACHMENT E - 2:

APPROVAL LETTERS FROM THE WESTAT INSTITUTIONAL REVIEW BOARD

Westat | An Employee-Owned Research Corporation

Memo

Date: March 14th, 2013

To: Terisa David, Project Director

From: Kerry Levin, Chair Westat IRB Kerry Levin

Subject: **Expedited Approval of FLASHE, Project 6053.01.01**
FWA 00005551

As Chair of the Westat Institutional Review Board (IRB), I reviewed the materials submitted for the following: **FLASHE, Project 6053.01.01.** The Westat IRB reviews all studies involving research on human subjects. This study is funded by National Cancer Institute.

The purpose of this study is to assess how daily lifestyle practices may affect the health of parents and their teenage children. Parents and children will each complete two on-line surveys, one about physical activity and the other will be about eating habits. In addition, some teenagers will be asked to participate in a part of the study that will measure physical activity levels. If selected, teens will wear a wrist accelerometer (a monitor that records body movement) for seven days in a row and fill out log recordings.

Gift cards ($5) will be provided for teens and their parents who complete each online survey. Additional gift cards ($20/$40) will be provided for participation in the motion sensing study.

Per 45 CFR 46, IRB regulations permit expedited review of certain activities involving minimal risk [45 CFR pt. 46.110 (b) 1 and 404]. This study was considered minimal risk and approved under expedited authority. Because obtaining consent from only one parent does not adversely affect the rights and welfare of the subjects, and that the research may not practicably be carried out without the waiver, the IRB also approved the request to waive permission of one parent or guardian [45 CFR 46.116 of Subpart A and 46.408 (b)]. Further, Per 45 CFR 46 117(c), documentation of informed consent is also approved for parent consent 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 March 14, 2014.
- In the interim, you are responsible for notifying the IRB Office 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
Nancy Weinfield

Westat | An Employee-Owned Research Corporation

Memo

Date: May 31st, 2013

To: Terisa Davis, Project Director

From: Kerry Levin, Chair Westat IRB Kerry Levin

Subject: **Expedited Amendment Approval of FLASHE, Project 6053.01.01**
FWA 00005551

As Chair of the Westat Institutional Review Board (IRB), I reviewed the materials submitted for the following: **FLASHE, Project 6053.01.01.** The Westat IRB reviews all studies involving research on human subjects. This study is funded by National Cancer Institute. The study was last reviewed on March 14, 2013.

This request is to approve an amendment to a previously approved protocol due to stipulations made by the National Cancer Institute IRB.

The regulations (45 CFR 46) permit expedited review of minor changes to previously approved activities. I am therefore approving the modifications under expedited authority. This study can be considered minimal risk and is approved under expedited authority.

As the Project Director you are responsible for the following:

- You are required to submit this study for a continuing review on or before March 14, 2014.
- In the interim, you are responsible for notifying the IRB Office 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
Nancy Weinfield