Supporting Statement A For:

Family Life, Activity, Sun, Health, and Eating (FLASHE) Study **(NCI)**

August 30, 2013

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LIST OF ATTACHMENTS

*Indicates an instrument.

This package is a request for OMB to approve the new submission titled, "The Family Life, Activity, Sun, Health and Eating Study" (FLASHE Study) for two years. The FLASHE Study takes a dyadic approach to examine psychosocial, generational (parent-adolescent), and environmental correlates of cancer preventive behaviors. FLASHE will examine the science of cancer and obesity prevention by examining correlates of cancer preventive behaviors, mainly diet, activity, and sedentary behaviors (but also examining other behaviors such as sleep, sun-safety, and tobacco) in new ways not previously addressed comprehensively on other surveys in samples of parents and their adolescent children. The survey's goal is to advance understanding of the dynamic relationship between the environment, psychosocial factors, and cancer preventive behaviors from a dyadic perspective. Data collected will ultimately be a public use dataset and resource to the research community. FLASHE will be collecting data from parents and their adolescent children using a web survey format with a final estimated sample size of 2,500 dyads, with motion sensing data collected in a subsample of 900 adolescents.

A. JUSTIFICATION

A.1 Circumstances Making the Collection of Information Necessary

The Public Health Service Act, Section 412 (42 USC *§* 285a-1) and Section 413 (42 USC *§* 285a-2) authorizes the National Cancer Institute (NCI) to establish and support programs for the detection, diagnosis, prevention and treatment of cancer; and to collect, identify, analyze and disseminate information on cancer research, diagnosis, prevention, and treatment.

The mission of the Health Behaviors Research Branch is to support research on cancer prevention behaviors and outcomes, which includes diet, physical activity, sedentary behavior, energy balance, obesity, skin cancer prevention (e.g., sun safety), genetic influences on behaviors and virus exposure. It provides leadership in these areas by focusing research on effective cancer prevention influences and approaches at multiple levels including individual, relational, environmental, and community-based. One important strategy to support the mission is to develop publically available datasets that allow the research community to examine correlates of cancer preventive behaviors and the role of the social and environmental context on these behaviors, such as diet and physical activity.

Current research and public health priorities at the NIH,[1] CDC,[2] and goals and objectives listed in Healthy People 2020[3] underscore the role of home and community environmental influences on public health burdens of obesity and overweight. A review of over 25 longitudinal studies found that overweight and obese youth were significantly at greater risk for becoming overweight and obese adults, which can subsequently increase the risk of chronic diseases across the life course (Singh, et al., 2008) (All references can be found in Attachment Q). These findings are particularly alarming, as recent NHANES data indicate approximately a third of all US children are overweight or obese (Ogden, et al., 2010).

Understanding correlates of obesity are a scientific priority for the NCI and the Health Behaviors Research Branch, as convincing evidence has identified the role of body fatness in increased risk for several cancers (Wolin, et al, 2010). Furthermore, behaviors associated with energy balance, such as physical activity and fruit and vegetable consumption have been shown to be associated with decreased cancer risk (American Institute for Cancer Research, 2007). Obesogenic behaviors may also cluster with other health risk behaviors such as sleep, sun-safety, sedentary behaviors and tobacco use and have an additive effect on cancer risk. Therefore, examining physical activity and dietary behaviors within the context of other health behaviors can enhance behavioral research efforts to understand correlates of these behaviors and ultimately reduce cancer risk (McTiernan, et al., 1998, Ma, et al., 2000, Schuit, et al., 2002, Doll and Peto, 1981, Hausdorf, et al, 2008).

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[1] http://www.obesityresearch.nih.gov/;

[2] http://www.cdc.gov/healthycommunitiesprogram/

[3] Healthy People 2020 goals and objectives for the nation http://www.healthypeople.gov/2020/topicsobjectives2020/overview.aspx?topicid=11

Families and the home environment are the crux of socio-environmental influences and they have a direct, mediating, and moderating role on children's health and development (Davison and Birch, 2001). Parents are of particular importance, as they directly determine their child's physical and social environment and indirectly influence their behaviors, habits, and attitudes (Ritchie, et al., 2005; Masse, et al, 2012). Recent research has also shown that parents may either mediate or moderate the relationship between school and community/neighborhood influences and children's behavior. Few studies have evaluated both parenting style and parenting practices within the context of childrens' and adolescents' diet, physical activity and other cancer preventive behaviors, utilizing a dyadic approach.

The FLASHE Study will collect data in adolescents and their parents across the multiple domains of environment and behavior, with a specific focus on familial relationships within the home environment (parent-adolescent) and key behavioral and psychosocial factors. Adolescence is a key developmental period in which behaviors learned and developed often also track into adulthood. Therefore, understanding what factors are most influential on development of key health promotion behaviors: diet and physical activity, sleep, sun safety, and tobacco during this developmental period can offer important information to help inform the field, as well as behavioral interventions in these areas.

The survey data offers the scientific community a tool for research and identification of key points of intervention by identifying associated psychosocial mechanisms for behavior change, based on extant behavior change theories and literature. FLASHE uses new measures (have not been previously included in other national surveys) for aiding in understanding the complexity of

health behaviors (i.e. emotion regulation, parenting and screen time, media exposure related to dietary behaviors). The survey includes other topics hypothesized to be related to cancer prevention, such as parenting styles and practices, foods available in the home, physical activity equipment available in the home, emotion regulation, and eating in the absence of hunger.

A.2 Purpose and Use of the Information

The current proposal builds from previous work in examining correlates of cancer preventive behaviors, specifically with regard to fruit and vegetable intake (5 A Day Customized Survey, OMB No. 0925-0560, exp. 3/31/2009) and Questionnaire Cognitive Interviewing and Pretesting (OMB No. 0925-0589, exp. 4/19/2011) to develop and refine the FLASHE surveys. The goal of FLASHE is to examine the correlates of obesogenic and cancer preventive behaviors among adolescents and their parents across intrapersonal, interpersonal (specifically, parent-child dyad), and broader contextual domains, including the community and home environments. The primary objectives include:

- Examine the direct and indirect associations between neighborhood/community environments, home, intrapersonal factors on obesogenic behaviors, specifically the role of the environment as a moderator of the relationship between psychosocial factors and behavior.
- Examine the role of relationships in the home (e.g. parent-child) on obesogenic behaviors, including the psychosocial mechanisms by which these relationships may be associated with obesogenic and cancer risk behaviors.

The secondary objectives include:

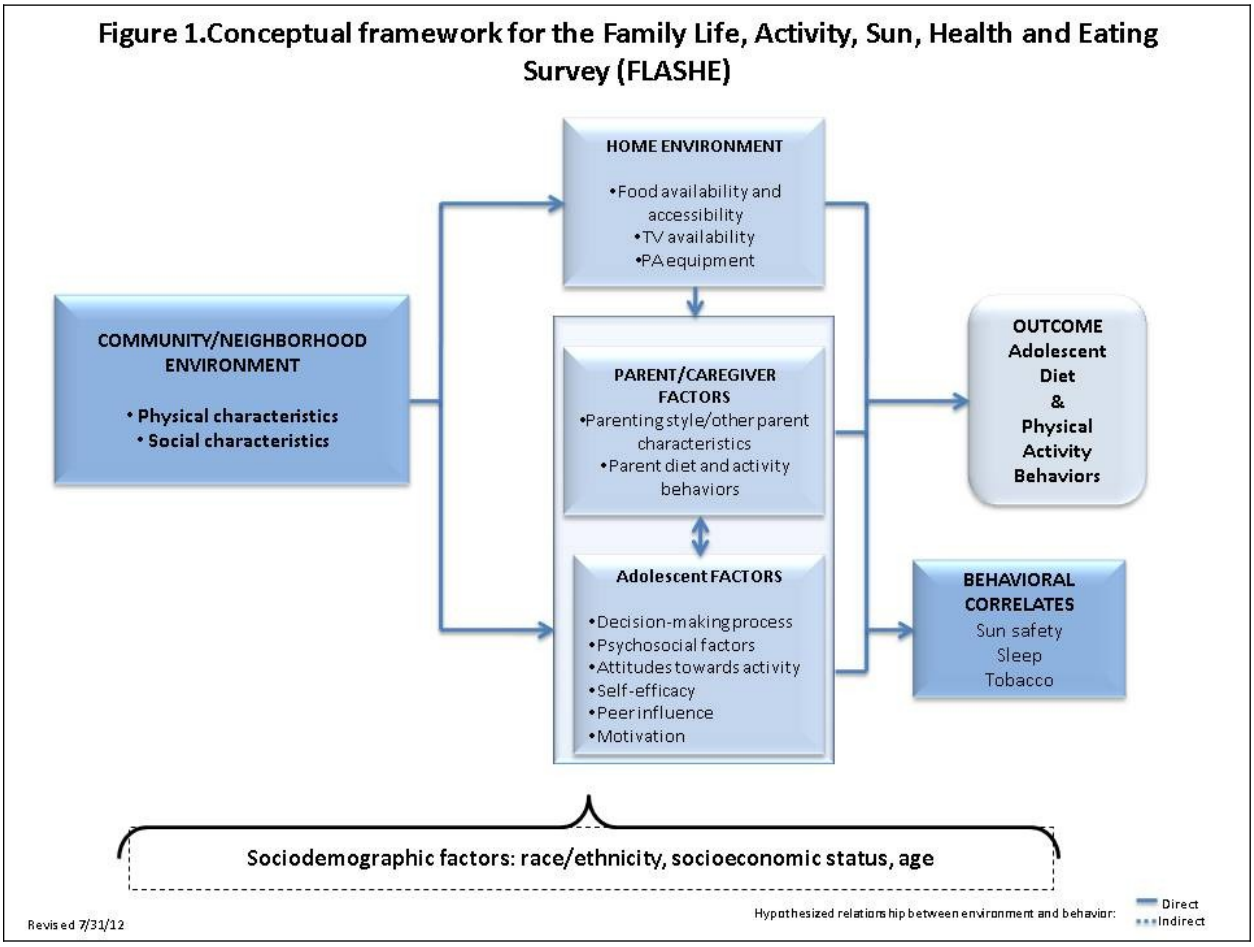
- Develop a dataset that can be used in concert with extant datasets that collect information related to child health (e.g. school policies such as the Classification of Laws Associated with School Students [CLASS], education, and economic data).
- Explore the feasibility of collecting data that may be enable calculation of objective measures of the environment (e.g., walkability, access to park space) for spatial analysis.
- Develop unique survey items for adolescent respondents that may be included in other health behavior surveillance studies, research, and/or intervention studies.

- Support the National Collaborative on Child Obesity Research (NCCOR) activities in which NCI/NIH is a partner, as well as the 2010 NIH-wide Strategic Plan for Obesity research objectives.

Research Questions

The FLASHE sampling will select parent-adolescent dyads and collect data on multiple domains including the neighborhood/community environment, home environment, parenting relationships, psychosocial factors and behaviors. In doing so, the survey data offers the research community a tool for research and identification of key points of intervention by identifying associated psychosocial mechanisms for behavior change based on extant behavior change theories and literature. FLASHE will also identify new measures for understanding the complexity of health behaviors and promotion (i.e. emotion regulation, parenting and screen time, media exposure). The FLASHE conceptual model is guided by social ecologic and behavioral psychosocial frameworks. This framework is described in Figure 1.

Figure 1.



Broadly, FLASHE Research Questions include (but are not limited to):

1) Home and Neighborhood Environment:

- Do psychosocial behavioral correlates (e.g. barriers to consuming fruits and vegetables and barriers to physical activity) mediate or are mediated by the home environment and ultimately what is their impact on diet and physical activity behaviors?
- Do psychosocial behavioral correlates mediate or are mediated by the community/neighborhood environment and ultimately what is their impact on diet and physical activity behaviors?

2) Parenting:

- What is the relationship between neighborhood and community context and parenting styles supportive of diet and physical activity behaviors?
- For example, in neighborhoods that are less safe and have higher levels of poverty, is a more restrictive parenting style (e.g. authoritairan) an adaptive strategy by providing a high level of supervision and support?

- For instance, is an authoritarian parenting style protective against adolescent physical inactivity and poor diet among families who live in low-income, unsafe neighborhoods?

3) Dyads:

- What are the joint and independent effects of both parent/caregiver's attitudes and adolescent attitudes towards intake of more healthful foods such as fruit and vegetables on adolescent dietary intake?
- How do parent/caregiver reported attitudes vary from adolescent perceptions?

The FLASHE Survey measures multiple constructs that are outlined in the conceptual model and others. These constructs were identified through a comprehensive literature review and consultation with teams of extramural scientific reviewers and collaborations with the Centers for Disease Control (CDC) and the National Collaborative for Childhood Obesity Research.

Briefly, the FLASHE study will utilize a web-based survey among parents and their adolescent children (ages 12-18 years old) and collect motion sensing data in a subset of adolescents. While the survey will be cross-sectional, each parent and adolescent dyad will be surveyed twice and at two different time points (phase 1: diet- focused survey and phase 2: physical activity-focused survey). Each survey will include measures of the neighborhood, home environment, parenting, and psychosocial domains, but items included within each domain will be specific to either diet or activity behavior. When possible, survey items are in parallel in adolescent and parent surveys to allow for dyadic analyses. More information on the methodology can be found in the Supporting Statement B.

Audiences for Data and Results

Understanding the role of correlates of cancer preventive behaviors (e.g., diet and physical activity) and other related factors are necessary to advance research and the promise of interventions to reach population level impact. FLASHE data will be made publically available

for users to access for individual research. The FLASHE project team will work with partner organizations (e.g. CDC, USDA, NCCOR and professional societies, such as the Society for Behavioral Medicine and the American Public Health Association) to disseminate data release and access information. The data collected in FLASHE will likely be used by junior, mid-level, and senior investigators for secondary data analysis, intervention development, and measurement identification in development of research grant proposals. Because of the large scope of the data collected and the limited availability of funds for researchers to conduct studies such as this on their own, these data will be of great interest and it is anticipated that it will be a highly used resource. Summary reports, articles, and presentations will be disseminated through multiple methods, including presentation at professional and research conferences, peer-reviewed publications, professional newsletters and listserves and the NCI website.

A.3 Use of Improved Information Technology and Burden Reduction

Information technology (IT) (e.g., web-survey data collection) will be the primary method to contact all study respondents and to collect study data. Study participants will receive study communications by email/text and will have access to the study website for information about FLASHE and to complete the study surveys. The initial invitation to participate in the study will include the web address for the study website and the potential participant's Personal Identification Number (PIN). For an explanation of how the use of the PIN reduces burden on the participant please see Section B.2. The use of IT for study contacts will reduce the overall burden on study participants by:

- Reducing the number of items that respondents have to receive in the mail;
- Ensuring respondents always know where to go for information about the study (study website);

- Ensuring respondents always know how to contact study staff (via email and/or toll free phone number available on website);
- Making each survey as short as possible through automated skip patterns; and
- Making each survey specific to respondents (via auto-fills) so that they have a clear understanding of the information being sought.

Selected adolescent study respondents will be asked to wear an accelerometer (to collect motion sensing data) to measure their activity level. The accelerometers will provide a more accurate indication of physical and sedentary activity than the traditional recall survey. Using this technology for an objective measure of activity eliminates the need for the study participants to complete a burdensome detailed diary of their daily activities and is the scientific standard for validating self-reported physical activity measures.

An IT system will be used to track respondents and store and maintain the data. This use of IT will increase the accuracy and efficiency of the data collection. In addition, this type of management system will allow participants to view and manage their progression through the study, thereby improving participant understanding, communication, and completion of tasks.

A Privacy Impact Assessment (PIA) has been initiated through NCI's Privacy Act Coordinator. See **Attachment A** for a draft of the PIA submitted.

A.4 Efforts to Identify Duplication and Use of Similar Information

To the best of our knowledge, FLASHE does not replicate any currently publically available data collected by the US Government. The development of FLASHE came from the scientific staff at

NCI and the public research community who helped identify priority areas of behaviorally-focused obesity and cancer prevention research and gaps in publically available data.

In efforts to avoid unnecessary duplication, the study team conducted an evaluation of existing surveillance data systems that are relevant to childhood obesity research. This work involved review of the National Collaborative of Childhood Obesity (NCCOR) Catalogue of Surveillance Systems (http://www.nccor.org/projects/catalogue/). It is a searchable web database including over 75 existing surveillance systems that contain data relevant to childhood obesity research. After searching this database, we found that none of these surveys or systems examined the multiple domains that are included in FLASHE and none of these data sources took a dyadic approach (e.g., parent report, adolescent report about themselves and vice versa, in a way that examines the relational context). In addition, no survey listed in the Catalogue examined psychosocial behavioral constructs or parenting to the extent that FLASHE will cover. FLASHE will collect new data and measures that have not previously been collected on the proposed scale or in a dyadic approach. Thus, information exactly like or corresponding in a way to serve the research purpose of FLASHE is not currently available.

In October 2011, the NCI advised NCCOR in identifing scientific priority areas in publically available data resources and research gaps in childhood obesity research. To identify these research priorities and perceived gaps in publically available data for childhood obesity researchers, NCOR conducted an online survey of NCCOR membership and others included on the NCCOR distribution list of researchers, federal and local government, and practitioners. A total of 516 people responded and results showed that the top priority rankings related to diet

related research (out of 8 domains) was the home food environment, the community environment, school environment, psychosocial correlates of dietary behaviors, and finally parenting styles and practices related to diet behaviors. The highest priority for physical activity was the community environment, including neighborhood access and policy influences, followed by the school environment, home environment, sedentary behaviors, and finally parenting styles and practices. Respondents reported the biggest gap was availability of survey data on the home environment followed by the community environment for both diet and physical activity. These data were used to identify priority research questions and measures for FLASHE.

The FLASHE development team also worked closely with the CDC, Division of Nutrition, Physical Activity and Obesity, scientific staff to focus on priority research questions and identify measures that had not already been collected in the FLASHE population of interest. Research meetings including the NCI “Cancer Prevention Begins at Home” held in 2011 and “Dyadic Processes Across the Cancer Continuum” held in 2010, provided feedback and an overview of current research and methods related to dyads and health, as well as the role of parents and parenting on cancer preventive health behaviors, such as diet and physical activity. Both of these meetings involved the invitation and participation of research scientists from numerous academic institutions who are experts in their field of study from across the country.

Two sets of scientific reviews were conducted in January 2012 and January 2013. The purpose of the scientific reviews was to have the survey items, constructs, and protocols for FLASHE reviewed by researchers external to the government for construct validity, item reliability,

parsimony with research questions and goals and to ultimately strengthen the scientific purpose of the FLASHE study to achieve the survey goals.

A.5 Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this study.

A.6 Consequences of Collecting the Information Less Frequently

The survey will be cross-sectional, each parent and adolescent dyad will be surveyed twice and at two different time points and with different surveys (phase 1: diet- focused survey and phase 2: physical activity-focused survey). Additionally, a subset of adolescents will complete the web-based survey daily for one week to collect motion sensing data.

A.7 Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

Because the sample for this study will be drawn from a Consumer Opinion Panel (COP), this will be a convenience sample which reduces the ability to generalize to the overall US population. However, generalizing to the US population is not the goal of the FLASHE study. Rather, FLASHE seeks to explore correlates and identify relationships for promotion of cancer preventive behaviors in dyads of adolescents and parents versus a surveillance study which would require a nationally representative sample to identify population-level behavioral point estimates.

Additionally, the subset of adolescents who participate in the Motion Sensing Study will be asked to report information daily for seven days. The seven day wear period is based on

previous research. Behavioral variation in physical activity monitor measures has typically been estimated using a measurement error model and the intraclass correlation coefficient. Total variation is reduced by increasing the number of days the device is worn. Seven wear days have been routinely used by researchers because it provides a sufficient number of days to achieve intraclass correlation of more than 80% in most populations, while also providing the opportunity to sample behavior on both week and weekend days (Mathews, et. al., 2012). Otherwise, FLASHE complies with all other guidelines of 5 CFR 1320.5.

A.8 Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

The 60-Day Federal Register notice soliciting comments on this study prior to initial submission to OMB was published on June 28, 2013, Vol. 78, No. 125, page 28996. One public comment was received on June 29, 2013 which commented on the expense and topic of the study and asked that the study instead examine the physical effects of genetically modified food. An email response was sent on July 8, 2013, stating, "Your comments will be taken into consideration. The Division of Cancer Prevention at the NCI supports research that studies the potential impact from a cell, tissue or organism and the pathways associated with disease processes."

FLASHE was developed through NCI's collaboration with: Westat Inc., the Centers for Disease Control and Prevention (CDC), and the National Collaborative for Childhood Obesity Research (NCCOR). During the development of FLASHE, an External Scientific Review was conducted twice (2012 and 2013) to get comments and feedback on the development of the FLASHE survey and protocols. A list and the contact information for the individuals consulted during the reviews can be found in **Attachment B.**

A.9 Explanation of Any Payment or Gift to Respondents

Study participants (both members of each dyad) will be contacted by email and each asked to complete two on-line surveys. To encourage participation, a $5 token of appreciation will be sent for each survey completed. Individuals will be sent $5 within 5 days of the completion of each survey, for a total of $10 as a token of appreciation for the completion of both surveys. Evidence has shown that small tokens of appreciation can increase survey response. In a meta-analysis of web surveys, Fang (2010) found that giving a material token of appreciation (e.g., money) increased the odds of survey completion by 16% compared with no token of appreciation. Further, the same meta-analysis found that the promise of a token of appreciation (when a respondent is told in advance that he/she will get a something after completion) increased the odds of completion by 19% over no promise of a token. Other specific studies support these findings. For example, Bosnjak (2003) found that the promise of a $2 token of appreciation increased response to a web survey of the members of a professional organization. In a mail survey, Petrolia et al (2009) obtained a 4% increase in response rate among general population respondents who were promised $5 in appreciation for their time over those offered nothing (24% vs. 20%). Because of the planned dyadic analysis in FLASHE, we feel it is critical to try to encourage both members of each dyad to complete the surveys. Offering small tokens of appreciation for the respondent's time will help ensure completed dyads.

For the Motion Sensing Study, we feel it is important to offer a token of appreciation to encourage compliance with the protocol. The adolescent will be asked to wear the device for seven consecutive days beginning on a pre-assigned day. Although research in this area is limited, in a review of studies using accelerometers, Matthews et al (2012) found that offering an a token of

appreciation for the respondent's time was the most influential factor in ensuring adolescent compliance to the study requirements (wearing the monitor as requested). Several large-scale studies have found similar results with adults. It is also important to offer a token of appreciation in order to ensure the return of government property (the accelerometers). NCI has a limited numbers of these devices (n=300) and the budget does not allow for more than a 5% loss rate. The device is of no value to those outside the study because they cannot be used for anything other than motion sensing and the data is not accessible without the device-specific software to download it. However, even with this lack of "street value," it is anticipated that there will be some level of device loss during the course of the study. To try to mitigate this loss, we would like to offer a token of appreciation to any study participant that returns the device, even if it has not been worn as instructed. There is a lack of literature to suggest an appropriate size of the token. Therefore, we propose an experiment to compare the effectiveness of a $20 token vs. $40 token of appreciation. Adolescents will be randomized to be offered one of these two tokens of appreciation for their participation in the Motion Sensing Study. Including this experiment in FLASHE will provide evidence for future studies on the size of the token of appreciation needed to ensure both compliance and device return.

A.10 Assurance of Confidentiality Provided to Respondents

The NIH Privacy Act Officer has reviewed this information collection and determined that the Privacy Act does apply. The data collection is covered by NIH Privacy Act Systems of Record 09-25-0200, "Clinical, Basic and Population-based Research Studies of the National Institutes of Health (NIH), HHS/NIH/OD" which was published in the Federal Register September 26, 2002 (Vol. 67, p. 60776) (**Attachment C**). Participants in this study will be subject to assurances and

safeguards as provided by the Privacy Act of 1974 (5 USC 552a), which requires the safeguarding of individuals against invasion of privacy. The Privacy Act also provides for the privacy of records maintained by a Federal agency according to either the individual's name or some other identifier. All staff working with FLASHE data will adhere to the provisions stipulated within that announcement.

Westat, the study contractor, has its own policy and procedures regarding confidentiality and a pledge that all employees must sign (see **Attachment D**). Westat provides all safeguards mandated by the Privacy Act to protect the privacy of data gathered for this study. Westat data security procedures comply fully with procedural safeguards for computerized records as outlined in the U.S. Department of Health and Human Service's General Administrative Manual under "Safeguarding Records Contained in Systems of Record" and specified by the National Institute of Standards and Technology Federal Information Processing Standards (FIPS).

Personally identifiable information (PII) will be collected as part of this data collection effort and includes: full name (adults), first name (adolescents), email address, (potentially) cell phone number, gender, age, race, ethnicity, highest level of education and behavioral information. All of this information is necessary to enable study staff to make contact and communicate with study participants. All selected dyads will be assigned a study ID. The study management system (SMS) will contain both the selected dyad members' names, email addresses and the study ID. Data from the surveys and accelerometers is maintained in a separate database from the SMS or address information. Motion Sensing Study data will be identified only through a study ID. During the study period, only a limited number of Westat project staff will have

access to the contact information which will be maintained on a restricted-access drive within the Westat firewall. Survey and accelerometer data will be maintained on a secured database within the Westat firewall and will be accessible by only a limited number of Westat project staff. Data will be identified only through the study ID. No names or identifiers will be used in reports or delivered to the NCI as part of the final dataset. At the completion of the data collection period, all respondent identification information will be destroyed.

Study procedures will be designed to make respondents feel as comfortable as possible while participating in FLASHE. These procedures will involve assuring respondents of the privacy of their responses and of the voluntary nature of their participation in the survey or any of its components, including the option to skip specific questions that they may prefer not to answer. The linkage between study ID and personal identifiers will be destroyed upon completion of the study and will not be included in the dataset received by NCI from the contractor.

The National Cancer Institute's Special Studies Institutional Review Board (IRB) reviewed and approved the FLASHE study on May 30, 2013 in accordance with 45 CFR 46. Westat's IRB reviewed and approved the FLASHE study on March 14, 2012 and then approved edits to the documentation based on the NCI IRB on May 31, 2013. Copies of the IRB approvals are found in **Attachment E**.

A.11 Justification for Sensitive Questions

Personally identifiable information (PII) will be collected as part of this data collection effort. Very few of the FLASHE research topics require collection potentially sensitive information. The great majority of the questions will be about respondents' exercise activities and diets. Behavioral information may be considered sensitive information. Additionally, race and ethnicity are collected.

A.12 Estimates of Annualized Burden Hours and Costs

Each parent participant will be asked to first enroll and consent for themselves and then their adolescent, which is estimated to take no longer than 10 minutes for each. The adolescent will then complete an assent of no more than 5 minutes. Then each parent and adolescent participant in FLASHE will complete two web surveys each: one focused on diet and one focused on physical activity. Respondents will be randomized to receive either the diet or physical activity survey first. The diet and physical activity content of each of these surveys will take approximately 15 minutes to complete. There is also a demographics survey section. Because demographics are not likely to change between the two surveys, the demographics section will be added to the survey the respondent is randomized to receive first. The burden of the survey that includes this demographics section goes up slightly to 20 minutes. In addition to the web surveys, a subsample of adolescents will be asked to wear an accelerometer for 7 days and the adolescent will also be asked to fill out a short log every day; estimated to take no more than 5 minutes per day to complete, for a total of 35 minutes over the course of information collection.

The sequence of instruments is:

Table A.12-1. Sequence of Study Instrument Administration

Activity	**Minutes to complete**	**Attachment Number**
1. Parent completes self-enrollment and consent	10 minutes	Attachment F
2. Parent completes enrollment and consent for adolescent	10 minutes	Attachment G-1
3. Adolescent completes assent for self	5 minutes	Attachment G-2
4. Parent and adolescent complete first survey		
a. Parent web survey including demographics	20 minutes	Attachment H
b. Adolescent web survey including assent and demographics	20 minutes	Attachment I
5. Parent and adolescent complete second survey		
a. Parent web survey	15 minutes	Attachment J
b. Adolescent web survey	15 minutes	Attachment K
6. Adolescent completes Wear Log instrument	35 minutes	Attachment L

The estimated annualized burden is 2,243 hours and a total of 4,483 hours annualized over the two year study period as shown in Table A.12-2.

Table A.12-2. Estimates of Annual Burden Hours

Form Name	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Annual Burden Hours
Enrollment and Consent (Attachments F, G-1 & G-2)	Parents (enrolling self)	1,250	1	10/60	208
	Parents (enrolling adolescent)	1,250	1	10/60	208
	Adolescents (assenting self)	1,250	1	5/60	104
Web survey with demographics (Attachments H & I)	Parents	1,250	1	20/60	417
	Adolescents	1,250	1	20/60	417
Web survey without demographics (Attachments J & K)	Parents	1,250	1	15/60	313
	Adolescents	1,250	1	15/60	313
Wear Log (Attachment L)	Adolescents	450	7	5/60	263
				TOTAL	2,243

The cost burden to respondents is the time required to complete the web surveys and complete the wear log. The cost for adults in the study is based on the mean hourly wage for all adult occupations of $22.01 per hour according to the Bureau of Labor Statistics data dated May 2012 (http:/www.bls.gov/bls/blswage.htm). The cost for adolescents is based on the national minimum wage of $7.25. The annual cost to the respondents is $33,177 and the total cost over two years is estimated to be $66,353 (Table A.12-3).

Table A.12-3. Annualized Cost to Respondents

Form Name	Type of Respondent	Number of Respondents	Total Annual Burden Hours	Hourly Wage Rate	Total Annual Cost
Enrollment (Attachments F, G-1 & G-2)	Parents (enrolling self)	1,250	208	$22.01	$4,578.08
	Parents (enrolling adolescent)	1,250	208	$22.01	$4,578.08
	Adolescents (assenting self)	1,250	104	$7.25	$754.00
Web survey with demographics (Attachments H & I)	Parents	1,250	417	$22.01	$9,178.17
	Adolescents	1,250	417	$7.25	$3,023.25
Web survey without demographics (Attachments J & K)	Parents	1,250	313	$22.01	$6,889.13
	Adolescents	1,250	313	$7.25	$2,269.25
Wear Log (Attachment L)	Adolescents	450	263	$7.25	$1,906.75
				TOTAL	$33,176.71

A.13 Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There are no direct costs to respondents other than their time to participate in the study.

A.14 Annualized Cost to the Federal Government

The largest cost to the federal government is to pay a contractor $800,000 to conduct the data collection and deliver data files. NCI's costs are based entirely on labor. It is estimated that the study will require about 0.75 FTE total per year spread over 2-3 scientists (behavioral scientists, statistician, psychologists) at the GS-14 level or above, totaling $210,000. These expenses are related to directing contractors, overseeing and solving problems as they arise, developing materials, supervising data collection, data coding, data cleaning, data analyses, and preparation of manuscripts and presentations. The annual cost to the Federal Government is estimated to be $505,000 (Table A.14).

Table A.14. Annual Costs to the Government

	Total Costs over 2 Years	Annual Costs
Contractor Costs per year	$800,000	$400,000
NCI Personnel Costs per year	$210,000	$105,000
Total Cost per year	$1,010,000	$505,000

A.15 Explanation for Program Changes or Adjustments

This is a new information collection.

A.16 Plans for Tabulation and Publication and Project Time Schedule

PROJECT TIME SCHEDULE	
Obtain sample from Consumer Panel (Ipsos)	3 months after OMB approval
Send out invitation emails	4 months after OMB approval
Data Collection (survey and motion sensing study conducted simultaneously)	5 months – 14 months after OMB approval
Data cleaning/weighting	15 months after OMB approval
Data analysis	15 months after OMB approval
Data dissemination	22 months after OMB approval

Methods of Dissemination

Findings from the FLASHE will be disseminated through multiple methods, including summary reports available in electronic and hard copy format. These summary reports will also be publicly accessible through the National Cancer Institute's Health Behaviors Research Branch website, http://cancercontrol.cancer.gov/brp/hbrb/. In addition, NCI staff will analyze the data and prepare presentations for national conferences and publish articles in peer-reviewed journals (in conjunction with other researchers). The NCI staff will work within NCI and with other federal agencies (e.g., CDC) and professional societies (e.g. the Society of Behavioral Medicine and the American Public Health Association) as well as research organizations (e.g. National Collaborative of Childhood Obesity Research) to disseminate the results and availability of data for public use.

A.17 Reason(s) Display of OMB Expiration Date is Inappropriate

NCI is not seeking an exception to the display of the OMB expiration date.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

NCI is not requesting an exception to the certification requirements.