# **National Health and Nutrition Examination Survey**

# **Supporting Statement A**

OMB No. 0920-0237

(Expires November 30, 2012)

# GenIC -NHANES National Youth Fitness Survey

## **Contact Information**

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# Supporting Statement (gen IC) National Health and Nutrition Examination Survey (0920-0237)

This is a request for a GenIC under the generic approval of the National Health and Nutrition Examination Survey (NHANES) (OMB No. 0920-0237, exp. November 30, 2012), conducted by the National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention, to conduct the NHANES National Youth Fitness Survey dress rehearsal and the NHANES National Youth Fitness Survey. The dress rehearsal will be conducted in late 2011and the survey will be conducted in 2012. The target population consists of children and youths (ages 3-15 years). Burden for these projects has already been approved; thus, no change to the burden is requested.

#### A. Justification

1. Circumstances Making the Collection of Information Necessary.

#### **Background**

One out of every three children in the U.S. is now overweight or obese, a condition that places them at greater risk of developing diabetes, heart disease, and cancer over the course of their lives. Regular physical activity in children and adolescents promotes health and fitness and may help to prevent obesity. Compared to those who are inactive, physically active youth have higher levels of cardiorespiratory fitness and stronger muscles. They also typically have lower body fat. Their bones are stronger, and they may have reduced symptoms of anxiety and depression. Youth who are regularly active also have a better chance of a healthy adulthood. While children and adolescents don't usually develop chronic diseases, such as heart disease, hypertension, type 2 diabetes, or osteoporosis, risk factors for these diseases can begin to develop early in life. Regular physical activity makes it less likely that these risk factors will develop and more likely that children will remain healthy as adults.

In October 2008, the federal government issued its first-ever Physical Activity Guidelines for Americans to provide science-based guidance on the types and amounts of physical activity that provide substantial health benefits for Americans. Guidelines for Children and Adolescents ask for 60 minutes or more of aerobic, muscle strengthening, or physical activity daily.

While the number of children in the U.S. who meet the Physical Activity Guidelines is unknown, the percentage of children who are physically active in the U.S. is declining. In the NHANES 2003-2006, a physical activity monitor was fielded for ages 6 years and older; in NHANES 1999-2004 cardiovascular fitness was reported as estimated maximal oxygen uptake (VO2max) from a treadmill test for ages 12-49 years; and in 2011, NHANES implemented a hand grip test of upper body muscle strength component for ages 6 years and older.

#### The NHANES National Youth Fitness Survey

NCHS has conducted a series of health and nutrition surveys <u>under the rubric of NHANES</u> since the early 1960s. The surveys are unique in that physical examination data are obtained from

national samples of the U.S. population. The examination component is conducted in mobile examination centers (MECs) that travel to fifteen survey locations per year. NHANES data have been the cornerstone for numerous national health and nutrition policy and surveillance activities.

The Secretary of Health and Human Service, Kathleen Sebelius, has dedicated Affordable Care Act (ACA) funds to Obesity Prevention and Fitness, one of four critical priorities for the Department. The Obesity Prevention and Fitness priority advances activities to improve nutrition and increase physical activity to promote healthy lifestyles and reduce obesity related conditions and costs. Departmental ACA funds will be used to conduct a NHANES National Youth Fitness Survey (NYFS) in 2012, simultaneously with the regular NHANES. This survey will be conducted among children 3-15 years old. The study will take place in the same locations as the full NHANES, but will be conducted in a separate mobile examination trailer customized specifically for the NYFS. There will be a dress rehearsal at two NHANES locations prior to the launching of the full NYFS. A Dress Rehearsal is the implementation of the survey content including all aspects of the content (including questionnaires and physical measures) before the formal sample begins in order to do finalalize all instruments before full survey data collection begins. The NYFS will be conducted with children who are not participants in the full NHANES.

- A subset of the current NHANES questions relevant to the NYFS will be asked of children. The physical activity questions (PAQ) have been increased.
- The physical measures in the NHANES NYFS include the following new measures ---NOT currently on the 2011-12 NHANES:
  - O Endurance and cardiovascular fitness (treadmill)
  - o Modified pull-up
  - O Plank (holding your body off the ground in a standardized position without moving)
  - O Total gross motor skill development
  - O Lower body muscle strength
  - o 3 Skin fold measurements
- These physical measures, currently on the 2011-12 NHANES, will also be included on the NHANES NYFS:
  - O Height, weight, waist circumference, arm length, leg length and arm circumference
  - O Physical Activity Monitor (PAM)
  - O Grip strength (Upper body strength)

Planning for the NHANES NYFS included conducting the NHANES Children's Physical Activity Feasibility Study (CPAFS). New physical measures or new age ranges for current physical measures on the NHANES were evaluated during the CPAFS. The CPAFS was conducted from June 27, 2011 through July 28, 2011 in a Community HANES trailer.

One hundred sixty-nine children and adolescents, ages 3-15 years, participated in the CPAFS. Participants were recruited locally. Staff from the Division of Health and Nutrition Examination Surveys (DHANES) served as examiners. Data from the study were delivered to NCHS and

analyzed by DHANES staff. The study was successful in identifying tests that worked well in the mobile examination center environment and issues that needed to be resolved for inclusion of the tests in the NHANES National Youth Fitness Survey described here.

One out of every three children in the U.S. is now overweight or obese, a condition that places them at greater risk of developing diabetes, heart disease, and cancer over the course of their lives. Regular physical activity in children and adolescents promotes health and fitness and may help to prevent obesity. Compared to those who are inactive, physically active youth have higher levels of cardiorespiratory fitness and stronger muscles. They also typically have lower body fat. Their bones are stronger, and they may have reduced symptoms of anxiety and depression. Youth who are regularly active also have a better chance of a healthy adulthood. While children and adolescents don't usually develop chronic diseases, such as heart disease, hypertension, type 2 diabetes, or osteoporosis, risk factors for these diseases can begin to develop early in life. Regular physical activity makes it less likely that these risk factors will develop and more likely that children will remain healthy as adults.

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## 2. Purposes and Use of the Information Collection

A study such as NHANES NYFS was envisioned under the rubric of the special studies and Community HANES described when this ICR was most recently renewed (Information Collection Request (ICR) Reference no. 201010-0920-007).

The proposed NHANES NYFS will provide additional data for use in monitoring the fitness of children in the U.S. A dress rehearsal for the NYFS will be conducted at two NHANES locations in late 2011 and the NYFS itself will be conducted concurrently with the NHANES in 2012, although the surveys will have separate operations. No households will have both NHANES and NYFS participants.

The components to be included in the NYFS are either administered in the current NHANES or were tested in the NHANES Children's Physical Activity Feasibility Study (CPAFS)(approved 4/29/2011). The CPAFS took place in Gaithersburg, Maryland from June 27 through July 28, 2011. The study was conducted by DHANES staff in a Community Health and Nutrition Examination Survey (CHANES) trailer refurbished for use in the study. One hundred sixty-nine

children ages 3-15 years participated in the study. Included in the CPAFS were one test to measure physical activity, five tests of muscle strength and endurance, and height, weight, and body mass index (BMI). The six CPAFS tests were selected by DHANES staff with the input of experts in the fields of physical activity and kinesiology.

The protocol for the NHANES National Youth Fitness Survey (and dress rehearsal) is provided in Attachment A.

3. Use of Information Technology and Burden Reduction

Information is unchanged from that presented in Information Collection Request (ICR) Reference no. 201010-0920-007.

4. Efforts to Identify Duplication and Use of Similar Information

Information is unchanged from that presented in Information Collection Request (ICR) Reference no. 201010-0920-007.

5. Impact on Small Businesses or Other Small Entities

Only individuals will be asked to participate. No small businesses will be involved in this data collection.

6. Consequences of Collecting the Information Less Frequently

This is a one-time data collection.

7. Special Circumstances Relating to the Guidelines for 5CFR1320.5

This data collection fully complies with regulation 5CFR1320.5.

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

Information is unchanged from that presented in Information Collection Request (ICR) Reference no. 201010-0920-007.

9. Explanation of any payment or gift to respondents.

We request the following remuneration for the NHANES National Youth Fitness Survey and dress rehearsal participant's examination.

Subgroup	NHANES NYFS
12-15	\$60
Under 12	\$40

The participants for the NHANES NYFS will be selected in the same neighborhoods as the regular NHANES participants by the same NHANES interviewing staff. All their appointments and reminders will be managed by the same Field Office staff as the regular NHANES. We request the same remuneration as regular NHANES participants even though the burden is different for the following three reasons. First, the children are being called upon to exert themselves in most of the components of the examination. Second, it would be extremely difficult operationally for the interviewers and office staff to manage two sets of remuneration levels. Additionally, there is some concern about neighbors talking among themselves about the remuneration levels.

A \$20 incentive is provided to the parent/guardian accompanying the child to the trailer. If participants' parent/guardian must hire a sitter to care for the children, they are reimbursed at \$5.25 an hour up to 6 hours. Participants' parent/guardian also receives a transportation allowance for driving to the trailer, or a taxi is provided. The remuneration for transportation allowance and for Physical Activity Monitor (PAM) participants are unchanged from that presented in Information Collection Request (ICR) Reference no. 201010-0920-007.

## 10. Assurance of Confidentiality Provided to Respondents

The Privacy Act of 1974 (5 U.S.C. 552a) "requires the safeguarding of individuals", and Section 308(d) of the Public Health Service Act (42 U.S.C. 242m) requires the safeguarding of both individuals and establishments against invasion of privacy. Contractors who collect information identifying individuals and/or establishments must stipulate the appropriate safeguards to be taken regarding such information. The Privacy Act also provides for the confidential treatment of records of individuals, which are maintained by a Federal agency according to either individual's name or some other identifier. This law also requires that such records in NCHS are to be protected from "uses other than those purposes for which they were collected."

The confidentiality of individuals participating in NHANES is protected by section 308(d) of the Public Health Service Act (42 USC 242m), which states:

"No information, if an establishment or person supplying the information or described in it is identifiable, obtained in the course of activities undertaken or supported under section...306,...may be used for any purpose other than the purpose for which it was supplied unless such establishment or person has consented (as determined under regulations of the Secretary) to its use for such other purpose and (1) in the case of information obtained in the course of health statistical or epidemiological activities under section...306, such information may not be published or released in other form if the particular establishment or person supplying the information or described in it is identifiable unless such establishment or person has consented (as determined under regulations of the Secretary) to its publication or release in other form..."

In addition, legislation covering confidentiality is provided according to section 513 of the Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA) (PL-107-347), which states:

"Whoever, being an officer, employee, or agent of an agency acquiring information for exclusively statistical purposes, having taken and subscribed the oath of office, or having sworn to observe the limitations imposed by section 512, comes into possession of such information by reason of his or her being an officer, employee, or agent and, knowing that the disclosure of the specific information is prohibited under the provisions of this title, willfully discloses the information in any manner to a person or agency not entitled to receive it, shall be guilty of a class E felony and imprisoned for not more than 5 years, or fined not more than \$250,000, or both."

Consequently, all information collected in NHANES will be kept confidential, with an exception for suspected child abuse.

## **Privacy Impact Assessment Information**

The NCHS Privacy Act Coordinator and the NCHS Confidentiality Officer have reviewed this package and have determined that the Privacy Act is applicable. This study is covered under Privacy Act System of Records Notice 09-20-0164 ("Health and Demographic Surveys Conducted in Probability Samples of the U.S. Population").

An Advance Letter, included in the NHANES National Youth Fitness Survey Protocol (Attachment A), is mailed to each household in the sample segments announcing the impending arrival of an NHANES interviewer and explaining the confidential treatment of their responses. The informed consent documents for the interview and examination each repeat the confidentiality assurance (also found in the protocol Attachment A).

It is the responsibility of all employees of NCHS, including NCHS contract staff, to protect and preserve all NHANES data (this includes all oral or recorded information in any form or medium) from unauthorized persons and uses. All NCHS employees as well as all contract staff have received appropriate training and made a commitment to assure confidentiality and have signed a "Nondisclosure Affidavit". Staffs of collaborating agencies are also required to sign this statement and agencies are required to enter into a formal Designated Agent Agreement with NCHS before access to non-public data is permitted. It is understood that protection of the confidentiality of records is a vital and essential element of the operation of NCHS, and that Federal law demands that NCHS provide full protection at all times of the confidential data in its custody. Only authorized personnel are allowed access to confidential records and only when their work requires it. When confidential materials are moved between locations, records are maintained to insure that there is no loss in transit and when confidential information is not in use, it is stored in secure conditions.

NCHS policy requires physical protection of records in the field, and has delineated these requirements for the data collection contractor. The contractor also has its own policy and procedures regarding assurance of confidentiality and a pledge that all employees involved in NHANES must sign. The contractor provides all safeguards mandated by Privacy ACT and Confidentiality legislation to protect the confidentiality of the data. The contractor's data security procedures comply fully with security requirements delineated by the Information

Resources Management Office of CDC.

It is NCHS policy to make NHANES data available via public use data files to the scientific community. Confidential data will never be released to the public. For example, all personal information that could be potentially identifiable (including participant name, address, survey location number, sample person number), are removed from the public release files. The NCHS Disclosure Review Board reviews all files that will be released, to assure that directly or indirectly identifiable data are not included.

## 11. Justifications for Sensitive Questions

Information is unchanged from that presented in Information Collection Request (ICR) Reference no. 201010-0920-007.

#### 12. Estimates of Annualized Burden Hours and Cost.

For the NYFS approximately 4,145 respondents will participate in some aspect of the survey (Table 1). As detailed below, of these, 2,270 (almost 55%) will complete the screening portion and then be screened out. Approximately 375 respondents will complete the screener and household interview sections, but decline to be examined. The remaining 1,500 will participate in the screener, household interview and the physical examination. Overall average burden is 1 hour per person. (The respondents who participate in all aspects of the survey can expect an estimated burden of 2.5 hours as documented in the signed informed consent documents for the NYFS (see protocol Attachment A). Burden for the 240 dress rehearsal participants is estimated to be the same as for survey participants. The grand total burden of dress rehearsal and NYFS respondents is 4,385.

## Dress Rehearsal (2011)

	Number of Individuals	Burden
MEC and questionnaire	240	2.5 hours
NYFS (2012)		
Screener only	2,270	5 min
Screener and questionnaire	375	1 hour
MEC and questionnaire	1,500	2.5 hours

#### TABLE 1 - ANNUALIZED BURDEN HOURS AND COSTS

Type of Respondent	Number of Respondents	Number of Responses per respondent	Average Burden per Response (in hours)	Total Burden Hours
2. NHANES National Youth Fitness Survey &	4,385	1	1	4,385

Dress Rehearsal Participants		
Total		4,385

## b. Cost to Respondents

Respondents are children and youth. There is no expected cost to these respondents because they do not typically work fulltime. Parents are reimbursed for travel expenses to bring children to the examination location.

13. Estimate of Other Total Annual Cost Burden to Respondents or Record Keepers

None.

#### 14. Annualized Cost to the Federal Government

The NYFS dress rehearsal and survey are funded solely through Affordable Care Act funds from DHHS. Estimated cost is \$5,670,000.

# 15. Explanation for Program Changes or Adjustments

No changes in the burden are requested. The burden was already budgeted and approved in Information Collection Request (ICR) Reference no. 201010-0920-007.

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

Table 16-1 PROPOSED TIME SCHEDULE: NHANES PLANNING, DATA RELEASE, AND REPORTING ACTIVITIES

		2011	2012	2013
Type of Activity	NYFS Dress Rehearsal Interviews Begin	October		
	NYFS Dress Rehearsal Exams Begin	November		
	NYFS Survey Interviews Begin	December		
	NYFS Survey Exams Begin		January	

NYFS Data Collection Ends		January
Tabular Reports		December

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

Information is unchanged from that presented in Information Collection Request (ICR) Reference no. 201010-0920-007.

18. Exceptions to Certification for Paperwork Reduction Act Submissions.

There are no exceptions to the certification.