

0925–0649. *Need and Use of Information Collection:* The HCS will address the need for a cross-cutting national study of community programs and policies and their relationship to childhood obesity. The HCS is an observational study of communities that aims to (1) determine the associations between community programs/policies and body mass index (BMI), diet, and physical activity for children; (2) identify the community, family, and child factors that modify or mediate the associations between community programs/policies and BMI, diet, and physical activity in children; and (3) assess the associations between programs/policies and BMI, diet and physical activity in children in communities that have a high proportion of African American, Latino,

and/or low-income residents. A total of 264 communities and over 21,000 elementary and middle school children and their parents will be part of this study. A HCS community is defined as a high school catchment area. The study examines quantitative and qualitative information obtained from community-based initiatives; community characteristics (e.g., school environment); measurements of children's physical activity levels and dietary practices; and children's and parents' BMIs. Results from the Healthy Communities Study may influence the future development and funding of policies and programs to reduce childhood obesity. Furthermore, HCS results will be published in scientific journals and will be used for the development of future research

initiatives targeting childhood obesity. *Frequency of Response:* One time. *Affected Public:* Families or households; businesses, other for-profit, and non-profit. *Type of Respondents:* Parents, children, community key informants (who have knowledge about community programs/policies related to nutrition, physical activity, and weight of children), food service personnel, physical education instructors, school liaisons, and physicians or medical secretaries. The annual reporting burden is as follows: *Estimated number of respondents:* 69,010; *Estimated Number of Responses per Respondent:* 1; and *Estimated Total Burden Hours Requested:* 29,657. The annualized cost to respondents is estimated at \$381,841. There are no capital, operating, or maintenance costs to report.

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden per response (in hours)	Estimated total annual burden hours requested
Parents (screening) .....	39,600	1	10/60	6,732
Parents/Caregivers .....	7,128	1	1.56	11,120
Second Parents .....	3,564	1	7/60	428
Parents who refuse to participate .....	880	1	10/60	150
Children .....	7,128	1	1.04	7,413
Key Informants (screening) .....	3,520	1	5/60	282
Key Informants .....	1,056	1	2.25	2,376
Food Service Personnel .....	352	1	5/60	28
District Food Service Administrator/Manager .....	88	1	30/60	44
Physical Education Instructors .....	352	1	15/60	88
School Liaisons .....	352	1	25/60	148
Physicians/medical secretaries .....	4,990	1	10/60	848
<b>Total .....</b>	<b>69,010</b>	<b>.....</b>	<b>.....</b>	<b>29,657</b>

*Request for Comments:* Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and

instruments contact: Dr. Sonia Arteaga, NIH, NHLBI, 6701 Rockledge Drive, MSC 7936, Bethesda, MD 20892–7936, or call non-toll free number (301) 435–0377 or Email your request, including your address to: [hcs@nhlbi.nih.gov](mailto:hcs@nhlbi.nih.gov).

*Comments Due Date:* Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

Dated: February 19, 2013.

**Lynn Susulske,**

*NHLBI Project Clearance Liaison, National Institutes of Health.*

**Michael S. Lauer,**

*Director, DCVS, National Institutes of Health.*

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**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Submission for OMB Review; Comment Request: Clinical Myttheries: A Video Game About Clinical Trials

**SUMMARY:** Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on June 13, 2012, page 35407 and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended,

revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

**Proposed Collection:** Title: Clinical Mytheries: A Video Game About Clinical Trials. *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* New England Research Institutes as a contractor for the National Heart Lung and Blood Institute is planning to create an engaging, informational “serious video game” for adolescents about clinical studies which: (1) Incorporates core learning objectives; and (2) dispels misconceptions. Two types of information collection are planned:

- Usability testing to understand game-play/usability. This information will be collected by focus group and will be digitally recorded 90 minute groups.

- A pre/post randomized trial to measure change in knowledge. This information will be collected electronically through on-line questionnaire.

The game will be incorporated with a larger initiative to provide information about clinical research (<http://www.nhlbi.nih.gov/childrenandclinicalstudies/index.php>). *Frequency of Response:* Once. *Affected Public:* Individuals. *Type of Respondents:* Adolescents—aged 8–14.

The annual reporting burden is as follows: *Estimated Number of Respondents:* 280; *Estimated Number of Responses per Respondent:* 1; *Average Burden Hours per Response:* Wave 1—90/60 (1.5 hours), Wave 2—80/60 (1.33 hours); and *Estimated Total Annual Burden Hours Requested:* 378. The annualized cost to respondents is estimated at: \$3,783. There are no Capital Costs to report. The Operating Costs to collect this information is estimated at \$42,425.00.

**Note:** The following table is acceptable for the Respondent and Burden Estimate information, if appropriate, instead of the text as shown above.

Form name	Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Qualitative Focus Group Discussion Guide and screener.	Adolescents—Wave one	30	1	90/60 (1.5 hours) ..	45
Screen pre post eval .....	Adolescents—Wave two	250	1	80/60 (1.33 hours)	333
Total .....	.....	280	.....	.....	378

**Request For Comments:** Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

**Direct Comments to OMB:** Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov) or by fax to 202-395-6974, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Victoria Pemberton, RNC, MS, CCRC, National Heart, Lung and Blood Institute, 6701

Rockledge Drive, Rm. 8109, Bethesda, MD 20892, or call non-toll-free number (301) 435-0510 or Email your request, including your address to: [pembertonv@mail.nih.gov](mailto:pembertonv@mail.nih.gov)

**Comments Due Date:** Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

Dated: February 8, 2013.

**Michael Lauer,**

Director, Division of Cardiovascular Diseases, National Heart, Lung, and Blood Institute, NIH.

Dated: February 12, 2013.

**Lynn Susulske,**

NHLBI Project Clearance Liaison, National Institutes of Health.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Government-Owned Inventions; Availability for Licensing

**AGENCY:** National Institutes of Health, Public Health Service, HHS.

**ACTION:** Notice.

**SUMMARY:** The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious

commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

#### FOR FURTHER INFORMATION CONTACT:

Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301-496-7057; fax: 301-402-0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

#### Java Software for Investigational Drug Clinical Research

**Description of Technology:** A Java based software application available for academic use and on a royalty-bearing basis for commercial licensing. The Investigational Drug Management System (IDMS) supports the operational needs of the investigation drug section of a pharmacy providing inventory management functions which fulfill the recordkeeping requirements defined in the Code of Federal Regulations related to the storage, labeling, handling, and dispensing of investigational drugs. The internet/browser based application interfaces with the Computerized Provider Order Entry (CPOE) system for