Dated: May 31, 2012.

Farzad Mostashari,

National Coordinator for Health Information Technology.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Announcement of Requirements and Registration for ''My Air, My Health Challenge''

AGENCY: Office of the National Coordinator for Health Information Technology, HHS. National Institute of Environmental Health Sciences, National Institutes of Health, HHS. *Award Approving Official:* Farzad Mostashari, National Coordinator for Health Information Technology.

ACTION: Notice.

SUMMARY: Environmental and public health are closely related and complementary fields—and their future depends on a closer understanding of those connections. New portable sensors have the potential to transform the way we measure and interpret the influence of pollution on health. These technologies can provide a picture that is more detailed and more personal, with dramatic implications for health care, air quality oversight, and individuals' control over their own environments and health.

The U.S. Environmental Protection Agency (EPA) and U.S. Department of Health and Human Service (HHS) [National Institute of Environmental Health Sciences (NIEHS) and Office of the National Coordinator for Health Information Technology (ONC)] envision a future in which powerful, affordable, and portable sensors provide a rich awareness of environmental quality, moment-to-moment physiological changes, and long-term health outcomes. Health care will be connected to the whole environment, improving diagnosis, treatment, and prevention at all levels.

Many of the first steps toward this future have already been taken. Prototype projects have developed portable air quality and physiologic sensors, and experimental analysis tools for handling data that is higher quantity, but often lower quality, than more traditional monitoring techniques. The ''My Air, My Health Challenge'' aims to build on this foundation. We are seeking solutions that integrate data from portable physiological and air quality monitors, producing a combined picture that is meaningful and usable. The statutory authority for this challenge competition is Section 105 of the America COMPETES Reauthorization Act of 2010 (Pub. L. 111–358) and section 103 of the Clean Air Act, 42 U.S.C. 7403. This challenge addresses the mission of the NIEHS to conduct and support programs with respect to factors in the environment that affect human health, directly or indirectly. 42 U.S.C. 285.

DATES: *Phase 1:* Effective on June 6, 2012. Submission period ends October 5, 2012, 11:59 p.m. et. *Phase 2:* Effective on November 19, 2012. Submission period ends May 19, 2013, 11:59 p.m. et.

FOR FURTHER INFORMATION CONTACT: Denice Shaw, EPA, 202–564–1108; Adam Wong, ONC, 202–720–2866.

SUPPLEMENTARY INFORMATION:

Subject of Challenge Competition

The ''My Air, My Health Challenge'' is a multidisciplinary call to innovators and software developers (''Solvers'') to enable near-real-time, location-specific monitoring and reporting of air pollutants and potentially related physiological parameters, using a personal/portable integrated system to assess connections between the two (''sensor systems''). The system must link air-pollutant concentrations with physiological data, provide geocoded and time-stamped files in an easy-to-use format, and transmit this data via existing networks to a central data repository provided by EPA and HHS.

The challenge is structured in 2 phases:

Phase 1—Project Plan (no more than 15 pages, not including appendices that may consist of diagrams/schematics, bibliography, and other supplementary materials).

1. Propose a plausible link between health outcomes and airborne pollutants (chemical species and/or particulates), and provide evidence to support a plausible and physiologically meaningful relationship between airborne pollutants and physiological metrics in a defined population.

2. Propose a prototype design and development plan for an integrated multi-sensor and data management system that may be easily worn or carried by individuals within the defined target community/population.

3. Conceptualize data generation, management (may include processing & on-board storage), and transmission functionality of the device.

4. Propose a small-scale proof-of-concept study to validate the proposed prototype.

5. Study design process must include input from the target community/population.

Phase 2—Proof-of-Concept Pilot Project.

6. Finalists attend an event for feedback, questions, and business/entrepreneurial resources prepared by Challenge sponsors (EPA, HHS ONC, NIEHS).

7. Solvers develop the proposed prototype and execute experimental validation of the system to bring together data from personal air quality and physiological monitors, showing how these types of data and sensors can be integrated for practical use by health and environmental agencies, and by individual citizens. Proof-of-concept data must illustrate the accuracy and precision of the raw data and of any processed data produced by the system.

Level of Focus for Health/Pollution connections: Systems must track airborne pollutants and physiological parameters for a known or plausible health-pollution link. Solvers must be able to justify their chosen combination with research citations and to optimize the air sampling parameters (volume, frequency, etc.) and physiological measurement parameters to provide resolution appropriate to the specific pollutant, or combination of pollutants, and related health implications. Challenge Sponsors will provide examples of such links for illustrative purposes (appended to the challenge announcement), but will not limit Solvers to these particular cases.

Sensor development: Solvers are not expected to develop novel sensors for this challenge, but are not restricted to commercially available sensors. They may use sensors that are currently in the development or piloting stage, but must show that the sensor will be ready to use in functional tests—at least at a small scale—in time for the Phase 2 proof-of-concept demonstration. Instruments must be well characterized in terms of precision, accuracy and sensitivity. Integrated sensor systems must be able to transmit data to the central repository (in real time, or store and forward) using existing data networks (e.g. 3G, LTE, or WiFi), or able to connect with personal devices (e.g., smart phones) that have such capability. Solvers must enable appropriate calibration and error checking capabilities, although these need not be onboard the portable monitoring components.

Data Requirements and Constraints: Data transmitted by the integrated devices to a centralized data repository must enable the following to be understood from transmitted data:

1. Indicators of device functionality, including any results of automated

system diagnostics, calibrations, or error logs

2. The device unique identifier, including any paired communication device identifier (particularly important if bidirectional communication functionality is proposed)

3. Date and time the data were collected/measurements made (start and end timestamp)

4. The location of the device during data collection (geocode)—if sampling occurs over several minutes or longer Solvers should consider that users may be using transportation and that analysis should ideally show locations between sample start and end

5. Raw measurement data (quantitative or semi-quantitative) as well as any processed data or combined

6. Quality control metrics indicating, for instance, whether the device is being worn/carried or functioning correctly. Error checking can occur either prior to or after data transmission, but is an essential component.

The preferred data transmission file format is comma separated value (.csv) or variants thereof. Alternatively, encrypted binary files are also acceptable. Encryption keys/codes should be provided to the Challenge Sponsors so that data can be accessed at the central data repository.

Pollutant Focus: Solvers will be required to include at least one air pollution metric—although at their discretion they may include multiple air pollution metrics and/or other environmental metrics such as noise level and UV exposure. The focus, however, will be on chemical and/or particulate air pollutants.

Physiological Parameter Focus: Solvers will be required to include at least one physiological metric—although at their discretion they may include multiple physiological metrics and/or other person-oriented metrics such as behaviors and social interactions. The focus, however, will be on physical parameters (e.g., heart rate, breathing, pulse oxygenation), and their connection to pollutants.

Physical Guidelines for Sensors: At least one component of the sensor system must be wearable or carryable, and all components should have a minimal burden and be minimally obtrusive. The overall sensor system must focus on personal and local metrics (i.e., measuring air quality in the immediate vicinity of the wearer). Wearable components must be the right size and weight for their target audience (e.g., no more than 300 g for a child). Sampling frequency and area must be appropriate to the pollutants and physiological metrics of interest, as well as to the context of data collection (e.g., by walkers, cyclists or passengers on public transportation). The sensor system must include an on-board data buffer for when network access is unavailable, and may also at the Solver's discretion include personal media to which data may be downloaded for permanent or temporary storage. Open source hardware and software are desired but not required.

Measurement Guidelines for Sensors: Accuracy, detection limit, measurement range, and sensitivity of all sensors must be at sufficient resolution to record health-relevant changes in air pollutant(s) and physiological marker(s). If processing of the data is required in order to achieve this (e.g., normalization, increasing signal-to-noise ratios), the Solver must include the algorithm and its scientific basis (i.e., previously collected data and/or appropriate citations) in their report. Alternatively, centralized processing that enables parsing of local data, in order to increase data robustness and reduce false positive signals, may be used. If such an approach is determined to be useful, Solvers must outline suitable strategies and/or boundary criteria. In either case, solvers must communicate the overall uncertainty level of the final system output

Community Involvement: The sensor system must address a need in a specific community or population. In addition to scientific evidence supporting that need, Solvers must also seek and document community input. Representatives of the affected community should provide feedback on the pilot project both during conceptualization (Phase 1), and throughout the pilot study (Phase 2). This is not intended to override the Solvers' scientific judgment on technical issues, but to ensure that the project is respectful of local knowledge, community identity, and needs. Projects must include feedback to the community regarding both technical success (e.g., whether sensors performed as planned) and results (e.g., any correlations found in the data).

Scaling and Future Plans: While Phase 2 requires only a small-scale proof-of-concept project, final submissions for this phase must include a description of how the project could or will be extended and expanded. In general, Solvers are asked to propose concrete next steps that might be carried out with more time or resources available.

Eligibility Rules for Participating in the Competition

To be eligible to win a prize under this challenge, an individual or entity shall have complied with all the requirements under this section and **Federal Register** Notice.

This challenge is open to any Solver who is (1) an individual or team of U.S. citizens or permanent residents of the United States who are 18 years of age and over, or (2) an entity incorporated in and maintaining a primary place of business in the United States. Foreign citizens can participate as employees of an entity that is properly incorporated in the U.S. and maintains a primary place of business in the U.S. Solvers may submit more than one entry.

Eligibility for Phase 2 is conditional upon being selected as a Phase 1 Finalist. Eligibility for a prize award is contingent upon fulfilling all requirements set forth herein. An individual, team, or entity that is currently on the Excluded Parties List (*https://www.epls.gov/*) will not be selected as a Finalist or Winner.

Employees of EPA, HHS, and the reviewers or any other company or individual involved with the design, production, execution, or distribution of the challenge and their immediate family (spouse, parents and step-parents, siblings and step-siblings, and children and step-children) and household members (people who share the same residence at least three (3) months out of the year) are not eligible to participate.

An individual or entity may not be a Federal entity or Federal employee acting within the scope of their employment. Federal employees seeking to participate in this challenge outside the scope of their employment should consult their ethics official prior to developing a submission. An individual or entity shall not be deemed ineligible because the individual or entity used Federal facilities or consulted with Federal employees during a competition if the facilities and employees are made available to all individuals and entities participating in the competition on an equitable basis.

Federal grantees may not use Federal funds to develop COMPETES Act challenge applications unless consistent with the purpose of their grant award. (Grantees should consult with their cognizant Grants Management Official to make this determination.) Federal contractors may not use Federal funds from a contract to develop COMPETES Act challenge applications or to fund efforts in support of a COMPETES Act challenge submission.

Liability and Indemnification: By participating in this competition, Solvers agree to assume any and all risks and waive claims against the Federal Government and its related entities, except in the case of willful misconduct, for any injury, death, damage, or loss of property, revenue, or profits, whether direct, indirect, or consequential, arising from participation in this competition, whether the injury, death, damage, or loss arises through negligence or otherwise. By participating in this competition, Solvers agree to indemnify the Federal Government against third party claims for damages arising from or related to competition activities.

Insurance: Based on the subject matter of the competition, the type of work that it will possibly require, as well as an analysis of the likelihood of any claims for death, bodily injury, or property damage, or loss potentially resulting from competition participation, Solvers are not required to obtain liability insurance or demonstrate financial responsibility in order to participate in this competition.

Registration Process for Participants

To register for this challenge participants may do any of the following:

- Access the *www.challenge.gov* Web site and search for the ''My Air, My Health Challenge''.
- Access the ONC Investing in Innovation (i2) Challenge Web site at:
  - *http://www.health2con.com/devchallenge/challenges/onc-i2-challenges/.*
  - A registration link for the challenge can be found on the landing page under the challenge description.
- Access the Innocentive challenge Web site at *www.innocentive.com/myairmyhealth.*

Amount of the Prize

- Phase 1: $15,000 each for up to four Finalists who are selected to move on to Phase 2.
- Phase 2: $100,000 to the Winner.

Awards may be subject to Federal income taxes.

Payment of the Prize

HHS and EPA prizes awarded under this competition will be paid by electronic funds transfer and may be subject to Federal income taxes. HHS and EPA will comply with the Internal Revenue Service withholding and reporting requirements, where applicable.

Basis Upon Which Winner Will Be Selected

The review panel will make selections based upon the following criteria in Phase 1:

- Strength of evidence and/or argumentation regarding the linkage between air pollutant and physiological effect.
- Potential significance of technology and eventual benefit to target population(s).
- Viability of proposed sensor technologies to detect and quantify pollutants and their effects, and provide physiologically relevant health and air quality data.
- Viability of the proposed data reporting technology (communication to a centralized data repository provided by EPA and HHS)
- Viability of the proposed project plan.
- Viability of the proposed instrument design as a wearable/portable device.
- Viability of the proposed proof-of-concept study (low complexity is preferred).
- Appropriate use of community input in designing proof-of-concept study.

The review panel will make selections based upon the following criteria in Phase 2:

- Sensors: Successful technical collection of both health and environmental data
- Data Reporting: Successful formatting and transmission of data
- Data processing and evaluation
- Community Involvement and Interaction

Additional Information

Intellectual Property Rights: Upon submission, each Solver warrants that he or she is the sole author and owner of the work, that the work is wholly original with the Solver (or is an improved version of an existing work that the Solver has sufficient rights to use—including the substantial improvement of existing open-source work) and that it does not infringe any copyright or any other rights of any third party of which Solver is aware. Each Solver also warrants that the work is free of malware.

(a) Copyright. By participating in this competition, each Solver hereby grants to the Federal government an irrevocable, paid-up, royalty-free, nonexclusive worldwide license to reproduce, distribute copies, display, create derivative works, and publicly post, link to, and share, the work or parts thereof, including any parts for which it has obtained rights from a third party, in any medium, for Federal purposes. User warrants that it has obtained rights to any parts of the work not authored by Solver adequate to convey the aforementioned license. (b) Inventions. Finalists hereby grant to the Federal government a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any invention throughout the world made by Finalists that, if patented, would cover the submission or its use.

Privacy, Data Security, Ethics, and Compliance

Solvers are required to identify and address privacy and security issues in their proposed projects, and describe specific solutions for meeting them.

In addition to complying with appropriate policies, procedures, and protections for data that ensures all privacy requirements and institutional policies are met, use of data should not allow the identification of the individual from whom the data was collected. Solvers are responsible for compliance with all applicable federal, state, local, and institutional laws, regulations, and policy. These may include, but are not limited to, HIPAA, HHS Protection of Human Subjects regulations, and FDA regulations. If approvals (e.g., from Institutional Review Boards) will be required to initiate project activities in Phase 2, it is recommended that solvers apply for approval at or before the Phase 1 submission deadline.

The following links are intended as a starting point for addressing regulatory requirements, but should not be interpreted as a complete list of resources on these issues:

HIPAA

Main link: *http://www.hhs.gov/ocr/privacy/index.html.*

Summary of the HIPAA Privacy Rule: *http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/index.html.*

Summary of the HIPAA Privacy Rule: *http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/index.html.*

Summary of the HIPAA Security Rule: *http://www.hhs.gov/ocr/privacy/hipaa/understanding/srsummary.html.*

Human Subjects—HHS

Office for Human Research Protections: *http://www.hhs.gov/ohrp/index.html.*

Protection of Human Subjects Regulations: *http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html.*

Policy & Guidance: *http://www.hhs.gov/ohrp/policy/index.html.*

Institutional Review Boards & Assurances: *http://www.hhs.gov/ohrp/assurances/index.html.*

Human Subjects—FDA

Clinical Trials: *http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm.*

Office of Good Clinical Practice: *http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/OfficeofScienceandHealthCoordination/ucm2018191.*

Consumer Protection—FTC

Bureau of Consumer Protection: *http://business.ftc.gov/privacy-and-security.*

Authority: 15 U.S.C. 3719.

Dated: May 31, 2012.

Farzad Mostashari,

National Coordinator for Health Information Technology.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30-Day 12–12BZ]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. chapter 35). To request a copy of these requests, call (404) 639–7570 or send an email to *omb@cdc.gov.* Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

Data collection for the residential care facility and adult day service center components of the National Study of Long-Term Care Providers—NEW—National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Section 306 of the Public Health Service (PHS) Act (42 U.S.C. 242k), as amended, authorizes that the Secretary of Health and Human Services (DHHS), acting through NCHS, ''shall collect statistics on health resources * * * [and] utilization of health care, including extended care facilities, and other institutions.''

NCHS seeks approval to collect data for the residential care facility (RCF) and adult day services center (ADSC) components of a planned new survey, the National Study of Long-Term Care Providers (NSLTCP). A one year clearance is requested.

As background here are some details on the plans for the whole study, of which this data collection is two components. The entire NSLTCP is being designed to (1) Broaden NCHS' ongoing coverage of paid, regulated long-term care (LTC) providers; (2) merge with existing administrative data on LTC providers (i.e. Centers for Medicare and Medicaid Services (CMS) data on nursing home, home health, and hospice care); (3) update data more frequently on LTC providers for which nationally representative administrative data do not exist; and (4) enable comparisons across LTC provider types and monitor the supply and use of these providers.

The data will be collected in the 50 states and the District of Columbia from two types of LTC facilities: 11,701 RCFs and 5,000 ADSCs. The data to be collected from RCCs and ADSCs include basic characteristics, services offered, staffing, and practices of providers, as well as distributions of the demographics, physical functioning, and cognitive functioning of users (RCC residents and ADSC participants) aggregated to the RCC/ADSC level.

Expected users of data from this collection effort include, but are not limited to CDC; other Department of Health and Human Services (DHHS) agencies, such as the Office of the Assistant Secretary for Planning and Evaluation and the Agency for Healthcare Research and Quality; provider associations, such as LeadingAge (formerly the American Association of Homes and Services for the Aging), National Center for Assisted Living, American Seniors Housing Association, Assisted Living Federation of America, and National Adult Day Services Association; universities; foundations; and other private sector organizations, such as AARP.

Expected burden from data collection is 30 minutes for respondents. We estimate that 10% of RCC and ADSC directors will be called for 15 minutes of data retrieval when there are errors or omissions in their returned surveys. There is no cost to respondents other than their time to participate. The total estimate of annualized burden is 8,769 hours.

ESTIMATED ANNUALIZED BURDEN TABLE

Type of respondent	Form name	Number of respondents	Number of responses/ respondent	Average burden/ response (in hours)
RCC Director	RCC Questionnaire	11,701	1	30/60
ADSC Director	ADSC Questionnaire	5,000	1	30/60
RCC and ADSC Directors	Data Retrieval	1,670	1	15/60

Kimberly S. Lane,

Deputy Director, Office of Science Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2012–13795 Filed 6–6–12; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Native Employment Works (NEW) Program Plan Guidance and Report Requirements.

OMB No.: 0970–0174.

Description

The Native Employment Works (NEW) program plan is the application for NEW program funding. As approved by the Department of Health and Human Services (HHS), it documents how the grantee will carry out its NEW program. The NEW program plan guidance provides instructions for preparing a NEW program plan and explains the process for plan submission every third