DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Research Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Office of Research Integrity (ORI) has taken final action in the following case:

Kenneth Walker, Ph.D., University of Pittsburgh: Based on the admission of the Respondent, ORI found that Dr. Kenneth Walker, former postdoctoral fellow, Department of Pediatrics, University of Pittsburgh (UP), engaged in research misconduct in research supported by National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institutes of Health (NIH), grant R01 DK081128.

ORI found that Respondent engaged in research misconduct by falsifying and/or fabricating data that were included in the following two (2) publications, one (1) submitted manuscript, and two (2) grant applications submitted to NIDDK, NIH:

- ''Deletion of fibroblast growth factor receptor 2 from the peri-wolffian duct stroma leads to ureteric induction abnormalities and vesicoureteral reflux.'' *PLoS One* 8(2):e56062, 2013 (hereafter referred to as ''*PLoS* 2013'')
- ''Fgfr2 is integral for bladder mesenchyme patterning and function.'' *Am J Physiol Renal Physiol.* 308(8):F888–98, 2015 Apr 15 (hereafter referred to as ''*AJPRP* 2015'')
- Unpublished manuscript submitted to *PLoS One* (hereafter referred to as the ''Manuscript'')
- R01 DK104374–01A1
- R01 DK109682–01

Specifically, ORI found that Respondent falsified and/or fabricated quantitative real-time polymerase chain reaction (qPCR) data to demonstrate a statistically significant or ''trend'' of statistical difference in the expression of renal or bladder urothelium and muscle developmental markers between control and experimental (mutant) mice, when there was none. The false qPCR data were reported in:

- *PLoS* 2013: Figure 2E
- *AJPRP* 2015: Figures 1E, 4C, 7G, 7J, 8F, 12A
- Manuscript: Figures 1C, 4C
- R01 DK104374–01A1: Figure 14E and text on pages 41, 42, 45
- R01 DK109682–01: Figures 10G and 11 and text on pages 43 and 45

Dr. Walker has entered into a Voluntary Settlement Agreement (Agreement) and has voluntarily agreed:

(1) To have his research supervised for a period of three (3) years, beginning on April 14, 2016; Respondent agrees that prior to submission of an application for U.S. Public Health Service (PHS) support for a research project on which the Respondent's participation is proposed and prior to Respondent's participation in any capacity on PHS-supported research, Respondent shall ensure that a plan for supervision of Respondent's duties is submitted to ORI for approval; the supervision plan must be designed to ensure the scientific integrity of Respondent's research contribution; Respondent agrees that he shall not participate in any PHS-supported research until such a supervision plan is submitted to and approved by ORI; Respondent agrees to maintain responsibility for compliance with the agreed upon supervision plan;

(2) that any institution employing him shall submit, in conjunction with each application for PHS funds, or report, manuscript, or abstract involving PHS-supported research in which Respondent is involved, a certification to ORI that the data provided by Respondent are based on actual experiments or are otherwise legitimately derived and that the data, procedures, and methodology are accurately reported in the application, report, manuscript, or abstract;

(3) to exclude himself from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant for period of three (3) years, beginning on April 14, 2016; and

(4) to the retraction and/or correction of the *PLoS* 2013 and *AJPRP* 2015 publications, as determined by the corresponding author.

FOR FURTHER INFORMATION CONTACT: Director, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (240) 453–8200.

Kathryn Partin,

Director, Office of Research Integrity.

[FR Doc. 2016–11062 Filed 5–10–16; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the National Coordinator for Health Information Technology; Announcement of Requirements and Registration for ''Move Health Data Forward Challenge''

AGENCY: Office of the National Coordinator for Health Information Technology, HHS.

ACTION: Notice.

SUMMARY: The Move Health Data Forward Challenge aims to incentivize participants to create an application programming interface (API) solution that utilizes the implementation specifications developed by the HEART Workgroup (Heart WG) to enable individuals to securely authorize the movement of their health data to destinations they choose. The statutory authority for this Challenge is Section 105 of the America COMPETES Reauthorization Act of 2010 (Pub. L. 111–358).

DATES:

Phase 1:

- Challenge launch: May 10, 2016
- Submissions due: September 8, 2016
- Evaluation period: September 9—October 14, 2016
- Phase 1 winners announced: October 31, 2016

Phase 2:

- Prototyping period begins: October 31, 2016
- Submissions due: January 12, 2017
- Evaluation period: January 12—February 10, 2017
- Phase 2 winners announced: February 23, 2017

Phase 3:

- Scaling period begins: February 23, 2017
- Submission period ends: May 1, 2017
- Phase 3 winners announced: May 31, 2017

FOR FURTHER INFORMATION CONTACT: Caroline Coy, *caroline.coy@hhs.gov* (preferred), 202–720–2932.

SUPPLEMENTARY INFORMATION:

Award Approving Official

Karen DeSalvo, National Coordinator for Health Information Technology.

Subject of Challenge

ONC participated with a number of security, privacy and health Information technology (health IT) stakeholders to launch the HEART WG. The HEART WG was developed to expedite the process of gathering representatives from many different health-related

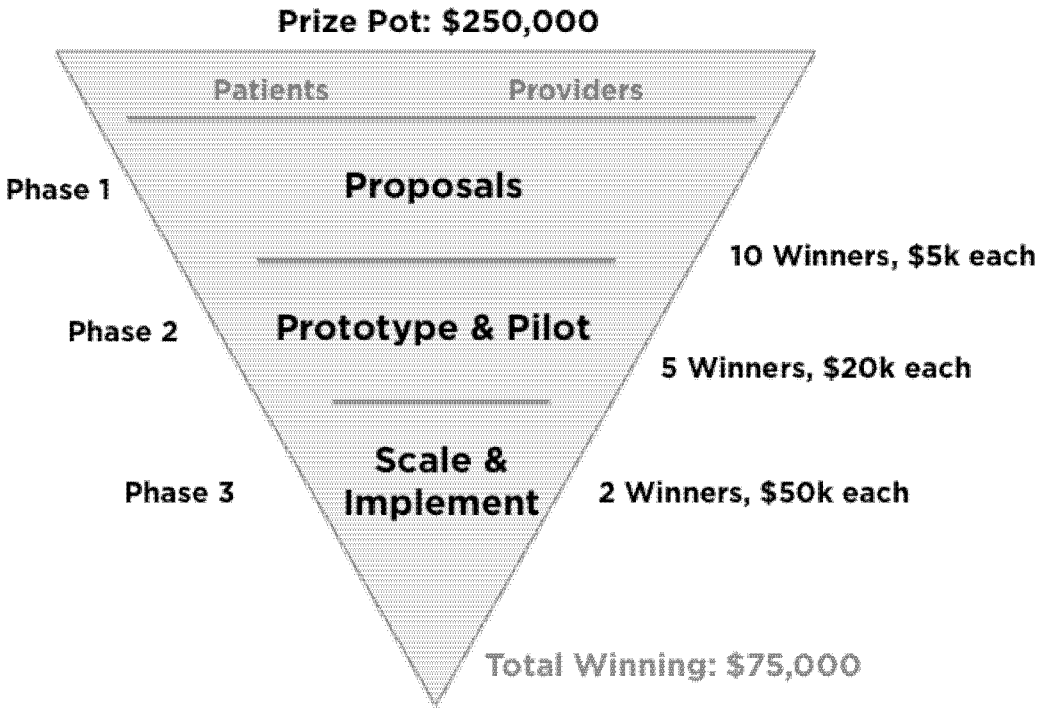
technical communities worldwide (private-sector, government and non-governmental organizations) working in areas such as patient authentication, authorization, and consent—to collaborate on developing open-source specifications. The impetus for creating the HEART WG was an effort by the Health IT Standards Committee (HITSC), which is charged with making recommendations to the National Coordinator for Health IT on standards, implementation specifications, and certification criteria for the electronic exchange and use of health information. In 2013, the HITSC was tasked with reviewing whether ONC should consider enhancing the portfolio of transport standards to support the use of RESTful services in health information exchanges in 2013 and recommended that ONC support the developing and piloting of standards including OpenID Connect and OAuth2.0. In 2015, the HITSC recommended tracking development and piloting of new and emerging technology specifications including the User Managed Access (UMA) profile of OAuth2.0 for obtaining consumer consent. The HEART WG has developed a set of privacy and security specifications (HEART implementation specifications) using the following open standards: OAUTH 2.0, OpenID Connect and User Managed Access (UMA). These specifications enable an individual to control the authorization of access to health-related data sharing APIs. The goal of this Challenge is to incentivize participants to create a Solution that utilizes the HEART implementation specifications to enable individuals to securely authorize the movement of their health data to destinations they choose.

Engaging individuals is a requirement of the Challenge. Participants are expected to engage individuals to test implementation of the Solution and enable processes that require individuals to authorize the release of their health data to a destination they choose. Participants are required to recruit individuals and obtain their authorizations to test implementation of the Solution on those individuals' health data. The data for the API and Solution should be provided by Phase 2 finalists.

The Challenge will have three phases. Phase 1 will award $5000 for up 10 finalists each based on the proposals they submit to the Challenge. Phase 1 winners will be eligible to proceed to Phase 2 which will award $20,000 for up to 5 finalists each based on the prototype of their Solution. Phase 2 winners will be eligible to proceed to Phase 3 which will award $50,000 for up to two winners each based on the participant's ability to implement their Solution. This multi-phased approach allows participants to assemble, implement and test their Solutions given the novel Solutions expected. The final phase of the Challenge will require finalists to demonstrate a consumer-facing Solution that incorporates the HEART implementation specifications and uses an API to enable consumers to authorize the movement of their health data to destinations they choose. This Challenge encourages participants who may apply independently or team with others including health IT developers, health care providers and other entities with the appropriate expertise related to this Solution. Lessons learned and the Challenge's results will be shared in order to support other organizations implementing solutions enabling consumer-mediated exchange.

Challenge Summary

The Challenge has three phases ending in two finalists each winning $75,000.



Phase 1—Proposals

The Proposal Phase is designed to allow participants to articulate Solutions to increase consumers' access to and sharing of their information within electronic health record systems. In this phase, participants are expected to describe the technical, operational, financial and business aspects of their proposed Solution. This includes but is not limited to the value proposition, target consumer population and/or target health care providers, key partners, implementation plan, timeline, cost structure and budget overview, key

activities and resources, and metrics for success (described below). The main goal of Phase 1 is for participants to articulate feasible and executable plans for innovative Solutions and demonstrate potential for impact.

A panel of independent reviewers will evaluate proposals and select finalists. Upon evaluating proposals and interview responses, judges will select up to 10 finalists to each receive a $5,000 award and advance to Phase 2 of the Challenge.

Phase 1 Submission Requirements

- Submissions in English and in pdf format.
- Submit by the deadline of September 8, 2016 using the online platform: *https://www.challenge.gov/?post_type=challenge&p=137291*
- General information about the participants and any team members
- Compliance with Health Insurance Portability and Accountability Act (HIPAA) if applicable
- Business Case (5 page maximum)
  - Includes an executive summary stating the value proposition
  - Describes how the proposed Solution will improve the exchange and accessibility of consumer health data
  - Describes the target consumer population and/or target health care providers
  - Describes the specific problem being solved
  - Description of the methods and technologies used to develop the Solution
  - Specify the HEART implementation specifications for data exchange that will be used by the proposed Solution
  - Financial overview that includes cost structure, projected revenue and expense budget, current funders and description of how funds will be used/allocated
  - Development plan and timeline
  - Describes key activities and resources required to employ the Solution
  - Plan to make the Solution readily available to consumers, for example to be used on existing mobile platforms or deployed on a public facing Web site
  - Metrics for success defined by applicant (*i.e.* Number of users of the Solution, money saved by using the Solution, time saved, increases in number of data exchanges between consumers and providers)
  - Potential risks and mitigation strategies, including security constraints
  - Description of the participant roles, responsibilities and capabilities
- Briefing deck presentation in pdf format of the Solution and use case(s) to provide a visual picture of the Project (10 slides maximum)
  - Content:
  - Brief description of proposed Solution and how the participants will use the HEART implementation specifications for consumer-mediated exchange of health information
  - Competitive advantage of the approach
  - Example use case
  - Proposed workflow & deliverables

Phase 2—Prototype & Pilot

The finalists of Phase 1 of the Challenge will then advance to a second phase focused on prototyping the Solution and demonstrating the effectiveness of the Solution and impact on consumer or provider health records accessibility and data exchange. The goal of Phase 2 is to demonstrate a viable Solution with high technological merit and potential to impact the quality of healthcare. Mentors will be available to help participants. Participants will have access to a community of experts to bring about high quality Solutions. Participants will test the HEART implementation specifications. Up to 5 finalists will receive $20,000 each and advance to Phase 3 of the Challenge.

Phase 2 Submission Requirements

- Submit by the deadline of January 16, 2017
- Submissions should be in pdf format
- Develop prototype using test data supplied by participant
- Provide an Implementation plan (up to 10 pages)
  - Describes key activities and resources required
  - Description of the pilot Project and budget
  - Provide timeline to go into production
- Video demonstration of the Solution and test results with live webinar
- Demonstration of the Solution's data security, accessibility, ease of data movement and HIPAA compliance if applicable

Phase 3—Scale & Implement

The final phase of the Challenge will involve testing the Solution in ''real-life'' situations. Engaging individuals is a requirement of this phase of the Challenge. Participants are expected to engage individuals to test implementation of the Solution and enable processes that require individuals to authorize the release of their health data to a destination they choose. Participants are required to recruit individuals to test implementation of the Solution. The data for this Solution should be provided by Phase 2 finalists. Participants are expected to engage and obtain authorization from a minimum of five (5) individuals to demonstrate and test implementation. This goal of Phase 3 is to accelerate the best Solutions in the health IT marketplace. This phase will also test the scalability of the Solution, the feasibility of implementation, and the impact of the intended outcomes. Phase 3 concludes with a presentation to ONC and judges during a live Demonstration (Demo) Day to showcase their Solutions and demonstrate impact. Two winners will each receive $50,000.

Phase 3 Submission Requirements

- Provide a description of the plan for engaging individuals in testing implementation of the Solution and processes for requiring individuals to authorize the release of their health data to a destination they choose
- Submissions must be in pdf format and should be no more than 10 pages
- Provide a narrative for the value proposition for the Solution and use case
- Report on progress in developing the Solution
- Demonstrate achievement of objectives set forth in the Business Case from Phase 1
- Description of lessons learned
- Provide concrete next steps for commercialization and/or broadened use, including how to attract consumers and/or providers to adopt and use the Solution
- Live demonstration of the Solution and results via webinar. This will not require travel by participants.
  - Demonstrate the capability to go live, scalability, HIPAA compliance (if applicable), and an interface optimized for consumers and/or providers

How to Enter

Participants can register by visiting: *https://www.challenge.gov/?post_type=challenge&p=137291* and click ''Submit Solution'' anytime during the proposal submission period stated above. Instructions and challenge information will be provided on the Challenge Web site. If potential participants are interested in finding team members for the Challenge, they may visit *https://www.challenge.gov/?post_type=challenge&p=137291* to browse ONC events and register online

anytime during the proposal submission period stated above.

Eligibility Rules for Participating in the Challenge

To be eligible to win a prize under this Challenge, an individual or entity:

1. Shall have registered to participate in the Challenge under the rules promulgated by the Office of the National Coordinator for Health Information Technology.
2. Shall have complied with all the stated requirements of the Move Health Data Forward Challenge
3. In the case of a private entity, shall be incorporated in and maintain a primary place of business in the United States, and in the case of an individual, whether participating singly or in a group, shall be a citizen or permanent resident of the United States.
4. May not be a Federal entity or Federal employee acting within the scope of their employment.
5. Shall not be an HHS employee working on their applications or Submissions during assigned duty hours.
6. Shall not be an employee of the Office of the National Coordinator for Health Information Technology.
7. Federal grantees may not use Federal funds to develop COMPETES Act challenge applications unless consistent with the purpose of their grant award.
8. 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.
9. No HHS or ONC logo—The product must not use HHS' or ONC's logos or official seals and must not claim endorsement.
10. A product may be disqualified if it fails to function as expressed in the description provided by the Participant, or if it provides inaccurate or incomplete information.
11. If applicable, the proposed Solution must be HIPAA compliant to be eligible for entry into the Challenge.
12. All individual members of a team must meet the eligibility requirements.

An individual or entity shall not be deemed ineligible because the individual or entity used Federal facilities or consulted with Federal employees during a Challenge if the facilities and employees are made available to all individuals and entities participating in the Challenge on an equitable basis.

Participants must 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 my participation in this prize contest, whether the injury, death, damage, or loss arises through negligence or otherwise. Participants are required to obtain liability insurance or demonstrate financial responsibility in the amount of $500,000, for claims by a third party for death, bodily injury, or property damage, or loss resulting from an activity carried out in connection with participation in a Challenge.

Participants must also agree to indemnify the Federal Government against third party claims for damages arising from or related to Challenge activities.

General Submission Requirements

In order for a Submission to be eligible to win this Challenge, it must meet the following requirements:

1. No HHS or ONC logo—The Solution must not use HHS' or ONC's logos or official seals and must not claim endorsement.
2. Functionality/Accuracy—A Solution may be disqualified if it fails to function as expressed in the description provided by the participant, or if it provides inaccurate or incomplete information.
3. Security—Submissions must be free of malware. Participant agrees that ONC may conduct testing on the API(s) to determine whether malware or other security threats may be present. ONC may disqualify the API(s) if, in ONC's judgment, the app may damage government or others' equipment or operating environment.

Registration Process for Participants

To register for this Challenge, participants can access *http://www.challenge.gov* and search for ''Move Health Data Forward Challenge.''

Prize

- Phase 1: up to 10 winners each receive $5000
- Phase 2: up to 5 winners each receive $20,000
- Phase 3: up to 2 winners each receive $50,000
- Total: up to $250,000 in prizes

Payment of the Prize

Prize will be paid by contractor.

Basis Upon Which Winner Will Be Selected

Eligible Challenge entries will be judged by a review panel composed of federal employees and experts in compliance with the requirements of the America COMPETES Act and the Department of Health and Human Services judging guidelines: *http://www.hhs.gov/idealab/wp-content/uploads/2014/04/HHS-COMPETITION-JUDGING-GUIDELINES.pdf.* The review panel will make selections based upon the criteria outlined below.

Phase 1

Participant Capabilities

- Is there appropriate expertise and capability to bring the idea to the testing stage?
- Does the participant have the resources available to carry out proposed work?

Impact Potential

- Does the proposed Solution have potential to improve the quality of health care?
- Is the proposed Solution using the HEART implementation specifications?
- Does the Submission describe how the Solution can be optimized for the greater population of consumers and/or providers?
- Is there a clear plan to make the Solution readily available to consumers on existing mobile platforms or a public-facing Web site?
- Is the Solution relevant to ONC priorities of improving the quality of health care?

Executability

- If applicable, does the Solution demonstrate its HIPAA compliance? Does the Solution utilize the HEART implementation specifications?
- Does the Submission demonstrate a reasonable and credible approach to accomplish the proposed objectives, tasks, outcomes and deliverable?
- Does the Submission address a pathway or timeline to broad use?
- Does the Submission clearly define potential risks?
- Does the Submission include a thorough description for the use of funds?

Phase 2

Technical Merit

- Does the Solution utilize privacy and security specifications/regulations?
  - If applicable, is the Solution HIPAA compliant?
  - Does the Solution enable an individual to control the authorization of access to data sharing APIs, using the HEART (HEART) implementation specifications?
- Does the Solution support consumer-mediated exchange?
- Is the consumer's health information easy to find, retrieve and access (data-accessibility)?

• Is the Solution easy to manage (ease of use, ease of data movement, user friendly)?

Viability

• Does the Solution present a deep understanding of the market for the Solution?
• Is there a clear advantage that differentiates this Solution from others?
• Is the Solution a model for real world implementation practical?
• Is the Solution economically viable and scalable/replicable?
• Are consumers and/or providers already participating (*e.g.* have signed up to test the Solution)?

Impact

• Does the participant present a theory or explanation of how the proposed Solution would improve the future of consumer-mediated health information sharing?
• Is there clear evidence of a health care need based on research for a specific consumer population, and is there evidence that Solution impacts this population?
• Could the Solution improve the experience of information sharing between consumers and their health care providers?
• Is the Solution's design human-centered so that it enables the consumer to understand and manage their health?

Phase 3

Impact

• Do the results indicate how the Solution will enable consumers to share data in a ''real-life'' setting?
• Does the Solution improve the experience of information sharing between consumers and their health care providers?

Deployability

• Is the Solution readily available to consumers to be used on existing mobile platforms or a public facing Web site?
• Is the Solution designed for ease of learning and ease of use by the target user population?

Scalability

• How scalable is the Solution in a real-world setting? How likely are cost efficiencies for delivery at greater scale?
• Is the user experience optimized for the greater population of consumers and/or providers?
• Is there a plan for getting consumers and/or providers to adopt and use the Solution?

Additional Information

General Conditions: ONC reserves the right to cancel, suspend, and/or modify the Challenge, or any part of it, for any reason, at ONC's sole discretion.

Intellectual Property: Each participant retains title and full ownership in and to their Submission. Participants expressly reserve all intellectual property rights not expressly granted under the challenge agreement. By participating in the Challenge, each entrant hereby irrevocably grants to the Government a limited, non-exclusive, royalty-free, perpetual, worldwide license and right to reproduce, publically perform, publically display, and use the Submission to the extent necessary to administer the challenge, and to publically perform and publically display the Submission, including, without limitation, for advertising and promotional purposes relating to the Challenge. This may also include displaying the results of the Challenge on a public Web site or during a public presentation.

Representation, Warranties and Indemnification

By entering the Challenge, each applicant represents, warrants and covenants as follows:

(a) Participant is the sole author, creator, and owner of the Submission;

(b) The Submission is not the subject of any actual or threatened litigation or claim;

(c) The Submission does not and will not violate or infringe upon the intellectual property rights, privacy rights, publicity rights, or other legal rights of any third party;

(d) The Submission does not and will not contain any harmful computer code (sometimes referred to as ''malware,'' ''viruses'' or ''worms''); and

(e) The Submission, and participants' use of the Submission, does not and will not violate any applicable laws or regulations, including, without limitation, HIPAA, applicable export control laws and regulations of the U.S. and other jurisdictions.

If the Submission includes any third party works (such as third party content or open source code), participant must be able to provide, upon request, documentation of all appropriate licenses and releases for such third party works. If participant cannot provide documentation of all required licenses and releases, the Federal Agency sponsor reserves the right, at their sole discretion, to disqualify the applicable Submission. Conversely, they may seek to secure the licenses and releases and allow the applicable Submission to remain in the Challenge, while reserving all rights with respect to such licenses and releases.

Participants must indemnify, defend, and hold harmless the Federal Government from and against all third party claims, actions, or proceedings of any kind and from any and all damages, liabilities, costs, and expenses relating to or arising from participant's Submission or any breach or alleged breach of any of the representations, warranties, and covenants of participant hereunder. The Federal Agency sponsors reserve the right to disqualify any Submission that, in their discretion, deems to violate these Official Rules, Terms & Conditions.

Authority: 15 U.S.C. 3719.

Karen DeSalvo,

National Coordinator for Health Information Technology.

[FR Doc. 2016–11102 Filed 5–9–16; 8:45 am]

BILLING CODE 4150–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: HHS–OS–0990–new–60D]

Agency Information Collection Activities; Proposed Collection; Public Comment Request

AGENCY: Office of the Assistant Secretary for Health, Office of Adolescent Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, announces plans to submit a Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting that ICR to OMB, OS seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on the ICR must be received on or before July 11, 2016.

ADDRESSES: Submit your comments to *Information.CollectionClearance@hhs.gov* or by calling (202) 690–6162.

FOR FURTHER INFORMATION CONTACT: Information Collection Clearance staff, *Information.CollectionClearance@hhs.gov* or (202) 690–6162.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the document identifier HHS–OS–0990–new–60D for reference.

Information Collection Request Title: Federal Evaluation of Making Proud Choices! (MPC!)