

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Health Center Program

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** Notice of class deviations from the requirements for competition and application period for the health center program.

**SUMMARY:** The Bureau of Primary Health Care (BPHC) is awarding funds to health centers transitioning to value-based models of care, improving the use of information in decision making, and increasing engagement in delivery system transformation.

**SUPPLEMENTARY INFORMATION:**

*Intended Recipient of the Award:* Approximately 1,380 Health Center Program award recipients.

*Amount of Competitive Awards:* Approximately \$90 million will be awarded in FY 2016 through a one-time supplement.

*Period of Supplemental Funding:* Anticipated 12 month project period is September 1, 2016 through August 31, 2017.

*CFDA Number:* 93.224.

**Authority:** Section 330 of the Public Health Service Act, as amended (42 U.S.C. 254b, as amended).

*Justification:* Targeting the Nation's neediest populations and geographic areas, the Health Center Program supports more than 1,300 health centers that operate over 9,000 service delivery sites in every state, the District of Columbia, Puerto Rico, the Virgin Islands, and the Pacific Basin. Nearly 23 million patients received comprehensive, culturally competent, quality primary health care services through the Health Center Program award recipients in 2014.

The fiscal year (FY) 2016 Health Center Program Delivery System Health Information Investment (DSHII) funding will provide formula-based, one-time support for the purchase of health information technology (health IT) enhancements to accelerate health centers' transition to value-based models of care, improve efforts to share and use information to support better decisions, and increase engagement in delivery system transformation efforts. Grant funds will help health centers make strategic investments to enhance their health IT, implement new clinical and administrative workflows, develop new reports, and better prepare providers and staff to use health IT and

data to achieve the quality, cost, and patient-centered goals of delivery system reforms. In addition, health centers that do not currently have a certified electronic health record (EHR) at all sites and in use by all providers must propose at a minimum to use DSHII funding to initiate and/or increase the number of sites and providers using a certified EHR. The investments will help health centers improve the quality and safety of services provided to the nation's most vulnerable populations.

**FOR FURTHER INFORMATION CONTACT:** Olivia Shockey, Expansion Division Director, Office of Policy and Program Development, Bureau of Primary Health Care, Health Resources and Services Administration at 301-443-9282 or [oshockey@hrsa.gov](mailto:oshockey@hrsa.gov).

Dated: July 18, 2016.

**James Macrae,**

*Acting Administrator.*

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**BILLING CODE 4165-15-P**

## 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:

*Zhiyu Li, Ph.D., Mount Sinai School of Medicine:* Based upon the evidence and findings of an investigation report by the Mount Sinai School of Medicine (MSSM) and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Zhiyu Li, former Postdoctoral Fellow, MSSM, engaged in research misconduct in research that was supported by National Cancer Institute (NCI), National Institutes of Health (NIH), grant R21 CA120017. ORI found that falsified and/or fabricated data were included in the following published papers, submitted manuscript, poster presentation, and grant applications:

- Li, Z., Fallon, J., Mandeli, J., Wetmur, J., & Woo, S.L.C. "A Genetically Enhanced Anaerobic Bacterium for Oncopathic Therapy of Pancreatic Cancer." *JNCI* 100(19):1389-1400, October 2008 (hereafter referred to as "*JNCI* 2008") (Retracted 02/2010).
- Li, Z., Fallon, J., Mandeli, J., Wetmur, J., & Woo, S.L.C. "The Oncopathic Potency of *Clostridium perfringens* is

Independent of its  $\alpha$ -Toxin Gene." *HGT* 20:751-758, July 2009 (hereafter referred to as "*HGT* 2009") (Retracted 03/2010).

- Li, Z., Fallon, J., Mandeli, J., Wetmur, J., & Woo, S.L.C. "Oncopathic Bacteriotherapy with Engineered *C. perfringens* Spores is Superior and Complementary to Gemcitabine Treatment in an Orthotopic Murine Model of Pancreatic Cancer." Submitted for publication in *Can. Res.* (hereafter referred to as the "*Can. Res.* Manuscript 2009").
- Li, Z., Fallon, J., Mandeli, J., Wetmur, J., & Woo, S.L.C. "Oncopathic Bacteriotherapy with *Cp/plc-/sod-/PVL* is Complementary to Gemcitabine Treatment for Pancreatic Cancer in Mice." Presented at the 12th Annual Meeting of the American Society of Gene Therapy, May 27-30, 2009.
- R21 CA120017-02
- R21 CA120017 Final Progress Report
- R01 CA130897-01
- R01 CA130897-01 A1
- R01 CA130897-01 A2
- R01 CA130897-01 A2 Supplemental Material
- R01 CA148697-01

The *JNCI* 2008 and *HGT* 2009 papers were retracted, and the *Can. Res.* Manuscript 2009 was withdrawn.

ORI found that the Respondent intentionally, knowingly, and recklessly engaged in research misconduct by falsely claiming to have generated recombinant *Clostridium perfringens* (*Cp*) strains, *Cp/sod-*, *Cp/sod-/PVL*, and *Cp/plc-/sod-/PVL*, to depict the effects of recombinant *Cp* strains on their ability to destroy cancer cells in a murine model, when these bacterial strains were not produced nor the data derived from them, and by falsifying histopathological data reported in fifty-seven (57) images in two (2) published papers, one (1) submitted manuscript, two (2) poster presentations, and seven (7) of Respondent's supervisor's grant applications and fabricating the corresponding nineteen (19) summary bar graphs that were based on those false images.

Specifically, Respondent trimmed and used portions of Figure 6 (right panel) of a draft R21 CA120017-01 grant application, representing an image of liver tumor two (2) days after injection of *Cp/plc-* bacteria, to represent unrelated results from different experiments in:

- Figures 5D and 7C (left panel), grant R21 CA120017 Final Progress Report
- Figure 6A, grant R01 CA130897-01
- Figures 9D and 17A (top left, middle, and right panels and bottom left panel), grant R01 CA130897-01 A1

- Figures 6D and 9C (left panel), grant R01 CA130897–01 A2
- Figure 2A (left, middle, and right panels) in R01 CA130897–01 A2 Supplemental Material
- Figures 4D and 7C (left panel), grant R01 CA148697–01
- Figure 4D (left panel), *JNCI* 2008
- Figure 3A (left panel), *HGT* 2009
- Figure 1A (left, middle and right panels), *Can. Res. Manuscript* 2009
- Figure labeled “Intratumoral Bacterial Titers and Quantification of Tumor Necrosis” (top left panel), *AGST* 2009 Poster presentation 2

Respondent trimmed and used portions of Figure 6C of R21 CA120017–02, representing pancreatic tumor five (5) days after injection of *Cp/sod*-bacteria, to represent results from different experiments in:

- Figures 5E, 6E and 7C (right panel), grant R21 CA120017 Final Progress Report
- Figures 9E, 10E, and 13C (right panel), grant R01 CA130897–01 A1
- Figures 6E, 7E and 9C (right panel), grant R01 CA130897–01 A2
- Figures 4E, 5E and 7C (right panel), grant R01 CA148697–01
- Figure 4D (right panel), *JNCI* 2008
- Figure 3A (middle and right panels), *HGT* 2009
- Figure labeled “Intratumoral Bacterial Titers and Quantification of Tumor Necrosis” (top right and middle panels), *AGST* 2009 Poster presentation 2

Respondent trimmed and used a portion of a figure that was reported as mouse pancreatic tumor tissue treated with control liposomes in four (4) figures (Figure 6D in R21 CA120017 Final Progress Report, Figure 10D in R01 CA130897–01 A1, Figure 7D in R01 CA130897–01 A2, and Figure 5D in R01 CA148697–01), to represent results from mouse pancreatic tumor tissue not treated with control liposomes in:

- Figures 7C (middle panel), grant R21 CA120017 Final Progress Report
- Figure 13C (left panel), grant R01 CA130897–01 A1
- Figures 9C (middle panel), grant R01 CA130897–01 A2
- Figure 7C (middle panel), grant R01 CA148697–01
- Figure 4D (middle panel), *JNCI* 2008
- Figure entitled “Oncopathic Potency of *Cp/sod*-/*PVL* in Tumor-bearing Mice” row C (left panel), *AGST* 2009 Poster presentation 1

Respondent falsified at least four (4) and possibly eight (8) images by using and relabeling Figures 4A (left panel), 4B (right panel), and 4B (left panel) in *JNCI* 2008 and Figure 1B (center panel) of *Cancer Res. Manuscript* 2009, to

represent different experimental conditions in Figures 3C (middle panel), 3B (left panel), 3C (right panel), and 3D (left panel) in *HGT* 2009 respectively.

Respondent trimmed and used portions of Figure 4E (right panel) in *JNCI* 2008, representing pancreatic tumor from mice injected with *Cp/sod*-/*PVL* bacteria, to represent mice injected with *Cp/plc*-/*sod*-/*PVL* bacteria in the following:

- Figure 2, row B (right panel), R01 CA130897 01 A2 Supplemental Material
  - Figure 3, row D (right panel), *HGT* 2009
  - Figure entitled “Intratumoral bacterial Titers and Quantification of Tumor Necrosis” (bottom right panel), *AGST* 2009 Poster presentation 2
  - Figure 1, row B (right panel), *Can. Res. Manuscript* 2009
- The Respondent also fabricated the resulting quantitative data in nineteen (19) summary bar-graphs based on the false histopathological images in:
- Figure 7C, grant R21 CA120017 Final Progress Report
  - Figures 13C and 17B, grant R01 CA130897–01 A1
  - Figure 9C, grant R01 CA130897–01 A2
  - Figure 2A–B, grant R01 CA130897–01 A2 Supplemental Material
  - Figure 7C, grant R01 CA148697–01
  - Figures 4A, B, D, and E, *JNCI* 2008
  - Figures 3A–D, *HGT* 2009
  - Figure 1C, *Can. Res. Manuscript* 2009
  - Figure entitled “Oncopathic Potency of *Cp/sod*-/*PVL* in Tumor-bearing Mice” graph (C) in *AGST* 2009 Poster presentation 1
  - Figure entitled “Intratumoral Bacterial Titers and Quantification of Tumor Necrosis” top and bottom row graphs in *AGST* 2009 Poster presentation 2

The following administrative actions have been implemented for a period of five (5) years, beginning on July 3, 2016:

- (1) Respondent is debarred from any contracting or subcontracting with any agency of the United States Government and from eligibility for, or involvement in, nonprocurement programs of the United States Government referred to as “covered transactions” pursuant to HHS’ Implementation (2 CFR part 376 *et seq*) of Office of Management and Budget (OMB) Guidelines to Agencies on Governmentwide Debarment and Suspension, 2 CFR part 180 (collectively the “Debarment Regulations”); and
- (2) Respondent is prohibited from serving in any advisory capacity to the U.S. Public Health Service (PHS) including, but not limited to, service on any PHS advisory committee, board,

and/or peer review committee, or as a consultant.

**FOR FURTHER INFORMATION CONTACT:** Director, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (240) 453–8800.

**Kathryn M. Partin,**

*Director, Office of Research Integrity.*

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**BILLING CODE 4150–31–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Indian Health Service

#### Office of Direct Service and Contracting Tribes National Indian Health Outreach and Education—Health Reform Funding Opportunity

*Announcement Type:* New Limited Competition.

*Funding Announcement Number:* HHS–2016–IHS–NIHOE–3–Health–Reform–0001.

*Catalog of Federal Domestic Assistance Number:* 93.933.

#### Key Dates

*Application Deadline Date:* August 25, 2016.

*Review Date:* August 29, 2016.

*Earliest Anticipated Start Date:* September 15, 2016.

*Proof of Non-Profit Status Due Date:* August 25, 2016.

#### I. Funding Opportunity Description

##### Statutory Authority

The Indian Health Service (IHS) Office of Direct Service and Contracting Tribes (ODSCT) and the Office of Resource Access and Partnerships (ORAP) is accepting cooperative agreement applications for the National Indian Health Outreach and Education III (NIHOE–III)–Health Reform funding opportunity that includes outreach and education activities on the following: The Patient Protection and Affordable Care Act, Public Law 111–148, as amended by the Health Care and Education Reconciliation Act of 2010, Public Law 111–152, collectively known as the Affordable Care Act (ACA), and the Indian Health Care Improvement Act (IHCIA), as amended. This program is authorized under the Snyder Act, codified at 25 U.S.C. 13, and the Transfer Act, codified at 42 U.S.C. 2001(a). This program is described in the Catalog of Federal Domestic Assistance under 93.933.

##### Background

The NIHOE III—Health Reform program carries out health program