which next generation sequencing (NGS) technology can now be used to detect the presence of clinically important pathogenic organisms in human specimens.

In contrast to human sequencing diagnostics, infectious disease sequencing diagnostics carry an absolute need for immediate and actionable results, sometimes within hours, as incorrect initial diagnoses potentially leads to fatalities. Furthermore, the broad range of specimen types (*e.g.,* urine, blood, cerebrospinal fluid (CSF), stool, sputum, etc.) and the large diversity of the infectious disease agents that can be present in the sample do not allow straightforward pre-analytical-, biochemical-, or bioinformatics processes. Each unique specimen type may require a different nucleic acid extraction procedure, a different library preparation protocol, and even a different bioinformatics algorithm to generate the final clinical result. The opportunity for repeat testing is expected to be limited due to a frequently small specimen quantity (*e.g.,* CSF) and the necessity to make a prompt and timely infectious disease treatment decision for the patient.

This draft guidance, when finalized, provides detailed information on the types of studies the FDA recommends to support a premarket application for these devices. This draft guidance specifically addresses Infectious Disease NGS devices that employ targeted or agnostic (metagenomic) sequencing, to identify the presence or absence of infectious disease organisms, and/or to detect the presence or absence of antimicrobial resistance and virulence markers. This draft guidance is not intended to address devices that utilize detection mechanisms other than nucleic acid based approaches. Further, this draft guidance does not apply to devices that are intended to screen donors of blood and blood components as well as donors of human cells, tissues, and cellular and tissue-based products for communicable diseases.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on ''Infectious Disease Next Generation Sequencing Based Diagnostic Devices: Microbial Identification and Detection of Antimicrobial Resistance and Virulence Markers.'' It neither creates nor confers any rights for or on any person and is not binding on FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov.* Persons unable to download an electronic copy of ''Infectious Disease Next Generation Sequencing Based Diagnostic Devices: Microbial Identification and Detection of Antimicrobial Resistance and Virulence Markers; Draft Guidance for Industry and Food and Drug Administration Staff; Availability'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1500016 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 801 and 809 have been approved under OMB control number 0910–0485; the collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; and the collections of information in 21 CFR part 814 have been approved under OMB control number 0910–0231.

Dated: May 9, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–11237 Filed 5–12–16; 8:45 am]

BILLING CODE 4164–01–P

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: In accordance with the Grants Policy and Administration Manual (GPAM) Part F: Chapter 2.b.34 and Part F: Chapter 3.b.16, the Bureau of Primary Health Care (BPHC) has been granted class deviations from the requirements for competition contained in the GPAM Part F: Chapter 2.a.1 and the requirements for application period contained in the GPAM Part F: Chapter 3.b.3 to expeditiously award funds to new health centers to improve access to services and clinical outcomes for the nation's most vulnerable populations through the patient centered medical home model.

SUPPLEMENTARY INFORMATION:

Intended Recipient of the Award: Health Center Program award recipients receiving Health Center Program funding for the first time in fiscal years (FYs) 2012, 2013, 2014, and 2015.

Amount of Competitive Awards: Approximately $10 million will be awarded in FY 2016 through a one-time supplement.

Period of Supplemental Funding: Anticipated 12 month project period is August 1, 2016, through July 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 FY 2016 Health Center Program Patient Centered Medical Home Supplement is a one-time supplemental funding opportunity that supports the upfront costs new Health Center Program award recipients face to become patient centered medical homes. Organizational transformation to achieve initial and more advanced levels of patient centered medical home recognition is costly. As of September 2015, data show that among the health centers eligible for this award only approximately 20 percent have achieved patient centered medical home recognition compared to 65 percent across all health centers. The

discrepancy suggests the efficacy of BPHC's past investments in FY 2011 and FY 2012 that supported health centers funded before FY 2012 achieve patient centered medical home recognition. The FY 2016 Health Center Program Patient Centered Medical Home Supplement is the first funding not tied to capital improvements that BPHC has offered to support health centers' evolution to patient centered medical homes since FY 2012.

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.*

Dated: May 5, 2016.

James Macrae,

Acting Administrator.

[FR Doc. 2016–11413 Filed 5–12–16; 8:45 am]

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:

John G. Pastorino, Ph.D., Rowan University School of Osteopathic Medicine: Based on an assessment conducted by Rowan University School of Osteopathic Medicine (RUSOM), the Respondent's desire to conclude the matter, and analysis conducted by ORI in its oversight review, ORI found that Dr. John G. Pastorino, Associate Professor, Department of Molecular Biology, RUSOM, engaged in research misconduct in research supported by National Institute on Alcohol Abuse and Alcoholism (NIAAA), National Institutes of Health (NIH), grant R01 AA012897 and National Cancer Institute (NCI), NIH, grant R01 CA118356.

ORI found that Respondent engaged in research misconduct by intentionally falsifying and/or fabricating data reported in the following eight (8) published papers, one (1) unpublished manuscript, and one (1) NIH grant application:

- *J. Cell. Sci.* 123:894–902, 2010 (hereafter referred to as ''*J. Cell. Sci.* 2010a'')
- *J. Cell. Sci.* 123:4117–4127, 2010 (hereafter referred to as ''*J. Cell. Sci.* 2010b'')
- *J. Cell. Sci.* 125:2995–3003, 2012 (hereafter referred to as ''*J. Cell. Sci.* 2012'')
- *J. Cell. Sci.* 126:274–288, 2013 (hereafter referred to as ''*J. Cell. Sci.* 2013'')
- *J. Cell. Sci.* 127:896–907, 2014 (hereafter referred to as ''*J. Cell. Sci.* 2014'')
- *Biol. Open.* 1–11:10;bio.014712, 2015 (hereafter referred to as ''*Biol. Open.* 2015'')
- *BioChim Biophys Acta.* 1827:38–49, 2013 (hereafter referred to as ''*BioChim Biophys Acta.* 2013'')
- *J. Biol. Chem.* 289:26213–26225, 2014 (hereafter referred to as ''*J. Biol. Chem.* 2014'')
- *J. Cell. Science,* Submitted manuscript, 2015 (hereafter referred to as ''*J. Cell. Sci.* manuscript 2015'')
- R01 HL132672–01, ''Regulation by Sirtuin-3 and Mitoneet of the Permeability Transition Pore in Heart during Ischemia/Reperfusion Injury,'' John Pastorino, Ph.D., Principal Investigator ORI found that Dr. Pastorino falsified and/or fabricated Western blot data for mitochondrial function related to cell/tissue injury, in fifty-eight (58) blot panels included in forty-two (42) figures in eight (8) publications, one (1) unpublished manuscript, and one (1) grant application. In the absence of valid Western blot images, the Respondent fabricated and/or falsified quantitative data in associated bar graphs, statistical analyses presented in figure legends, and related text.

Specifically, ORI found that Respondent duplicated images, or trimmed and/or manipulated blot images from unrelated sources to obscure their origin, and relabeled them to represent different experimental results in:

- Figures 2A, 2C, 3B, 5A, 7B, and 8A in *J. Cell. Sci.* 2010a
- Figures 2B, 5A, 6A, and 6B in *J. Cell. Sci.* 2010b
- Figures 1A, 2A, 2B, 4C, 5A, 5B, 6A, 7A, 7B, and 7C in *J. Cell. Sci.* 2012
- Figures 4F, 5H, and 6A in *J. Cell. Sci.* 2013
- Figures 1B, 2B, 2C, 3A, 3B, and 4D in *J. Cell. Sci.* 2014
- Figures 3A and 6B in *Biol. Open* 2015
- Figure 2A in *BioChim Biophys Acta.* 2013
- Figures 1B, 3A, 4D, 5E, and 6C in *J. Biol. Chem.* 2014
- Figure 3A in *J. Cell. Sci.* manuscript 2015
- Figures 3, 8A, 12, and 13A in R01 HL132672–01 NIH grant application

Dr. Pastorino has entered into a Voluntary Exclusion Agreement (Agreement) and has voluntarily agreed for a period of five (5) years, beginning on April 27, 2016:

(1) To exclude himself from any contracting or subcontracting with any agency of the United States Government and from eligibility 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 OMB Guidelines to Agencies on Governmentwide Debarment and Suspension, 2 CFR part 180 (collectively the ''Debarment Regulations'');

(2) that he will neither apply for nor permit his name to be used on any application, proposal, or other request for funds to the United States Government or any of its agencies, as defined in the Debarment Regulations; Respondent will further ensure that during the period of the voluntary exclusion, he will neither receive nor be supported by funds of the United States Government and its agencies made available through grants, subgrants, cooperative agreements, contracts, or subcontracts, as discussed in the Debarment Regulations; and

(3) to exclude himself 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) 453–8200.

Kathryn Partin,

Director, Office of Research Integrity.

[FR Doc. 2016–11317 Filed 5–12–16; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Request for Information for Developing the National Cancer Moonshot Initiative

SUMMARY: This Request for Information (RFI) describes ways in which the cancer research community and public can provide new ideas and comment on proceedings of the National Cancer Advisory Board (NCAB) Blue Ribbon Panel under the umbrella of the National Cancer Moonshot Initiative.

DATES: Responses should be submitted to the National Cancer Institute (NCI), National Institutes of Health (NIH) on or before 5:00 p.m. EST on July 1, 2016.