• An indication of whether the facility compounds from bulk drug substances, and if so, whether it compounds sterile or nonsterile drugs from bulk drug substances.

Registration information should be submitted to FDA electronically using the Structured Product Labeling (SPL) format and in accordance with section IV of the FDA guidance entitled ''Providing Regulatory Submissions in Electronic Format—Drug Establishment Registration and Drug Listing.'' Under the final guidance, outsourcing facilities may request a waiver from the SPL electronic submission process by submitting a written request to FDA explaining why the use of electronic means is not reasonable.

This information collection supports the Agency guidance discussed above. We estimate that approximately 62 outsourcing facilities (''number of respondents'' and ''total annual responses'' in table 1, row 1) will annually submit to FDA registration information using the SPL format as specified in the guidance, and that preparing and submitting this information will take approximately 4.5 hours per registrant (''average burden per response'' in table 1, row 1). We expect to receive no more than one waiver request from the electronic submission process annually (''number of respondents'' and ''total annual responses'' in table 1, row 2), and that each request should take approximately 1 hour to prepare and submit to us (''average burden per response'' in table 1, row 2).

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Compounding outsourcing facility	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Electronic Submission of Registration Information Using SPL Format	62	1	62	4.5	279
Waiver Request From Electronic Submission of Registration Information	1	1	1	1	1
Total					280

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: June 15, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning Legislation, and Analysis.

[FR Doc. 2017–12838 Filed 6–19–17; 8:45 am]

BILLING CODE 4164–01–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:

Brandi M. Baughman, Ph.D., National Institutes of Health (NIH): Based on Respondent's admission and analysis conducted by ORI, ORI found that Dr. Brandi M. Baughman, former Intramural Research Training Awardee, National Institute of Environmental and Health Sciences (NIEHS), NIH, engaged in research misconduct in research supported by National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), NIH, grant R01 DK101645 and the NIEHS, NIH, Postdoctoral Intramural Research Training Award (IRTA).

ORI found that falsified and/or fabricated data were included in eleven (11) figures in *PLoS One* 11(10):e0164378, 2016 (hereafter referred to as ''*PLoS One* 2016'').

ORI found that Respondent falsified and/or fabricated data and text published in *PLoS One* 2016, in Figures 2, 3, 4, 5, 6, 8, S1, S2, S3, S4, and S5, by claiming that a screening strategy of the kinase focused libraries, PKIS and 5K, was performed, when original data do not exist to support the claims. Respondent also claimed that three (3) inhibitory compounds for the inositol phosphate kinase, PPIP5K, were identified from the 5K library, when these compounds, UNC10112646, UNC10225354, and UNC10225498, were not part of the data set for the 5K library. Specifically, Respondent falsified and/or fabricated the characterization of the inhibitor compounds in:

• Figures 2 and 3 results for Z'-factor, %CV, signal:background ratio, and a 10-point dose response titration experiment for inhibitor UNC10225354

• claims in the text of *PLoS One* 2016 that eight molecules from the PKIS library and fifteen molecules from the 5K library inhibited PPIP5K activity by >50%

• Figure 4D results for the inhibition by UNC10112646, UNC10225354, and UNC10225498, in dose response assays against the kinase domain of PPIP5K

• Figures 5A and 5B results for isothermal titration calorimetry (ITC) assays for quantifying intermolecular interactions between PPIP5K and the inhibitors, UNC1011264 and UNC10225498, and Figure S5 for UNC10225354

• Figure 6 results for the analysis of the mechanisms of inhibition of PPIP5K by UNC10112646 and UNC10225498

• Figures 8A and 8B results for high performance liquid chromatography (HPLC) analysis for the effects of UNC10112646 or UNC10225498 on PPIP5K activity and IP6K activity

• Figures S1–S4 for experimental results further characterizing UNC10112646, UNC10225498, and other inhibitors, when the results were not supported by the experimental records.

As a result of Respondent's admission, NIH recommended that the *PLoS One* 2016 paper be retracted.

Dr. Baughman has entered into a Voluntary Settlement Agreement with ORI, in which she voluntarily agreed:

(1) To have her research supervised for a period of three (3) years beginning on May 17, 2017; Respondent agreed to ensure that prior to the submission of an application for U.S. Public Health Service (PHS) support for a research project on which 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 agreed that she will not participate in any PHS-supported research until a plan for supervision is submitted to and approved by ORI; Respondent agreed to maintain responsibility for compliance with the agreed upon supervision plan;

(2) that for a period of three (3) years beginning on May 17, 2017, any institution employing her 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 herself 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 a period of three (3) years, beginning on May 17, 2017; and

(4) as a condition of the Agreement, to the retraction or correction of *PLoS One* 11(10):e0164378d, 2016 (PMID: 27736936).

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

Kathryn M. Partin,

Director, Office of Research Integrity.

[FR Doc. 2017–12744 Filed 6–19–17; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[CFDA Number: 93.085]

Office of Research Integrity; Awards Unsolicited Proposal for the Professionalism and Integrity in Research Program

AGENCY: Office of Research Integrity, Office of the Assistant Secretary for Health, Department of Health and Human Services.

ACTION: Notice of Award of a single-source unsolicited grant to Washington University in St. Louis, Missouri.

Recipient: Washington University, St. Louis, Missouri.

Purpose of the Award: Grant to provide remediation training through the Professionalism and Integrity in Research Program (PI Program) to promote research integrity and prevent research misconduct.

Amount of Award: $135,763 in Federal Fiscal Year (FFY) 2017 funds and estimated $135,665 in FFY 2018 funds subject to the enactment of appropriations and availability of funds.

Project Period: July 1, 2017—June 30, 2019.

SUMMARY: The Office of Research Integrity (ORI) announces the award of a single-source, grant in response to an unsolicited proposal from Washington University, St. Louis, Missouri. The proposal submitted was not solicited either formally or informally by any federal government official.

ORI performed an objective review of the unsolicited proposal from Washington University to expand and evaluate the Professionalism and Integrity in Research Program (PI Program), the only remediation program for researchers who violate expectations for the responsible conduct of research. Based on an external and internal review of the proposal, ORI determined that it has merit.

There is a strategic importance of access to this type of training. Research misconduct involving Public Health Service (PHS) support is contrary to the interests of PHS and the federal government, the health and safety of the public, the integrity of research, and the conservation of public funds. Participants in the PI Program will demonstrate better research compliance and integrity outcomes, such as developing better, more ethical research practices. These outcomes will promote research integrity and help prevent future research misconduct.

This award is being made non-competitively because there is no current, pending, or planned funding opportunity announcement under which this proposal could be competed. ORI has identified three additional key reasons to support rationale for awarding this unsolicited proposal:

1. ORI's federal regulation directs us to focus on remediation of Respondents who have been found to commit research misconduct, and the PI Program permits a pathway for that remediation after any sanctions have been completed.

2. Washington University is uniquely positioned to provide this type of training. As the only remediation program for researchers, the grantee has developed a comprehensive and intensive program that will improve research compliance and integrity outcomes.

3. With this experience, Washington University is well known in the research community and is an important service to PHS funded institutions. The program has a robust and unique process for assessment and data analysis.

Legislative Authority: Sec. 301 of the Public Health Service Act, 42 U.S.C. 241

FOR FURTHER INFORMATION CONTACT: Kathryn Partin at *kathryn.partin@hhs.gov* or by telephone at 240–453–8200.

Dated: June 13, 2017.

Kathryn M. Partin,

Director of the Office of Research Integrity.

[FR Doc. 2017–12747 Filed 6–19–17; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR16–136: Using the NIMH Research Domain Criteria (RDoC) Approach to Understand Psychosis.

Date: July 5, 2017.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Julius Cinque, MS, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5186, MSC 7846, Bethesda, MD 20892, (301) 435–1252, *cinquej@csr.nih.gov.*

Name of Committee: AIDS and Related Research Integrated Review Group; Behavioral and Social Consequences of HIV/AIDS Study Section.

Date: July 13–14, 2017.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Ritz-Carlton Hotel, 1700 Tysons Boulevard, McLean, VA 22102.

Contact Person: Mark P Rubert, Ph.D., Scientific Review Officer, Center for