

and to describe best practices for FDA and sponsors when interacting on these topics. The guidance is available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requesting-fda-feedback-combination-products>. In the **Federal Register** of December 26, 2019 (84 FR

70976), we published a notice announcing the availability of the draft guidance that included an analysis under the PRA and solicited public comment on the proposed collection of information for CPAMs. One comment was received in support of the

collection but suggested no change in FDA's burden estimate.

Respondents to the information collection are sponsors of medical products, including combination products. We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

| 21 CFR section; activity | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response (hours) | Total hours |
|------------------------------------|-----------------------|------------------------------------|------------------------|-------------------------------------|-------------|
| 3.7; request for designation | 53 | 1 | 53 | 24 | 1,272 |
| Pre-RFD submissions | 83 | 1 | 83 | 24 | 1,992 |
| CPAMs requests | 3 | 1 | 3 | 25 | 75 |
| Total | | | | | 3339 |

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

For RFDs and pre-RFDs, our estimate is based on the number of submissions received from October 1, 2018, to September 30, 2019. We assume 1 submission per respondent, for an annual average of 53 RFD submissions, and 83 pre-RFD submissions and assume that each submission requires an average of 24 hours to prepare and submit to FDA.

Our estimate for CPAM requests is based on future activity in light of the minimal use of CPAMs to date; FDA has received two CPAM requests since the enactment of the Cures Act in December 2016. We estimate one CPAM request will be received per year by each medical product center (Center for Biologics Evaluation and Research, Center for Drug Evaluation and Research, and Center for Devices and Radiological Health). We assume it will take sponsors approximately 25 hours to compile and submit the recommended information. Because we expect burden associated with application submissions is already captured by approved information collection requests for drug, biologic, and medical device applications, respectively (approved under OMB control numbers 0910–0001, 0910–0338, and 0910–0231), we do not include burden associated with application submissions captured by these programs in this information collection request.

Dated: November 18, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–26062 Filed 11–24–20; 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: Findings of research misconduct have been made against Dr. David J. Panka (Respondent), former Harvard Medical School (HMS) Instructor of Medicine, and former HMS Associate Professor of Medicine at Beth Israel Deaconess Medical Center (BIDMC). Dr. Panka engaged in research misconduct in research supported by U.S. Public Health Service (PHS) funds, specifically National Cancer Institute (NCI), National Institutes of Health (NIH), grants P50 CA093683 and P50 CA101942. The administrative actions, including supervision for a period of three (3) years, were implemented beginning on November 9, 2020, and are detailed below.

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

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

Dr. David J. Panka, Harvard Medical School and Beth Israel Deaconess Medical Center: Based on the report of an inquiry conducted by BIDMC and HMS and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Panka, former HMS Instructor of Medicine, and former HMS Associate Professor of Medicine at

BIDMC, engaged in research misconduct in research supported by PHS funds, specifically NCI, NIH, grants P50 CA093683 and P50 CA101942.

ORI found that Respondent engaged in research misconduct by intentionally, knowingly, and/or recklessly falsifying and/or fabricating Western blot images by selectively cutting, flipping, reordering, and reusing the same source images or non-correlated images to represent different results in the following three (3) published papers and one (1) conference presentation:

- The Raf inhibitor BAY 43–9006 (Sorafenib) induces caspase-independent apoptosis in melanoma cells. *Cancer Res.* 2006 Feb 1; 66(3):1611–9 (hereafter referred to as “*Cancer Res.* 2006”). Retraction in: *Cancer Res.* 2019 Oct 15;79(20):5459.

- Differential modulatory effects of GSK–3b and HDM2 on sorafenib-induced AIF nuclear translocation (programmed necrosis) in melanoma. *Mol Cancer* 2011 Sep 19;10:115 (hereafter referred to as “*Mol Cancer* 2011”).

- Effects of HDM2 antagonism on sunitinib resistance, p53 activation, SDF–1 induction, and tumor infiltration by CD11b+/Gr-1+ myeloid derived suppressor cells. *Mol Cancer* 2013 Mar 5;12:17 (hereafter referred to as “*Mol Cancer* 2013”).

- Presentation #5328, “BAY 43–9006 induces apoptosis in melanoma cell lines”, presented during Cellular and Molecular Biology session #63 “(Apoptosis 4: Chemotherapeutic Agents II)” on April 20, 2005, at the 96th Annual American Association for Cancer Research (AACR) meeting, held in Anaheim, California (hereafter referred to as the “2005 AACR Presentation”).

Specifically, ORI found that Respondent knowingly, intentionally, and/or recklessly falsified and/or fabricated:

- Western blot images in twelve (12) figures of three (3) published papers and one (1) conference presentation by editing, reusing, and relabeling the same source images or the non-correlated blots to represent different results from different experiments. Specifically:

—Respondent reused and relabeled the same source bands to falsely represent different protein expression in the following two figures in *Cancer Res.* 2006 and to represent more than one lane within a single row:

- Figure 1A, bottom row, in *Cancer Res.* 2006, representing MEK expression in A375, A2058, and SK MEL 5 cells treated by different doses of Bay 43–9006
- Figure 2C, bottom row, in *Cancer Res.* 2006, representing the expression of Vinculin in the same three cell types without or with Bay 43–9006 treatment at different time points

—Respondent reused and relabeled the same source bands to falsely represent different protein expression in two figures as follows and to represent more than one lane within a single row:

- Figure 5, bottom row, in the 2005 AACR Presentation, representing the expression of Total Bad in A375 cells with different treatments
- Figure 2C, second row, in *Cancer Res.* 2006, representing the expression of Bax in three different cell types

—Respondent reused and relabeled the bands that were used for Figure 4, bottom row, in *Cancer Res.* 2006, representing ERK expression in A2058 cell type with different treatments at different time points, to falsely represent the expression of ERK in three different cell types in Figure 1A, second row, in *Cancer Res.* 2006.

—Respondent reused and relabeled the same source bands to falsely represent unrelated experimental results in two rows of Figure 3A in *Cancer Res.* 2006 as follows:

- Figure 3A, fourth row, in *Cancer Res.* 2006, representing the expression of pBad ser 75 in A2058 cell type with different treatments at different time points
- Figure 3A, seventh row, in *Cancer Res.* 2006, representing pBad ser 75 expression in A375 cell type with the same treatments and at the same time points as the representation of

the fourth row

—Respondent reused and relabeled the source bands to falsely represent unrelated experimental results in two rows of Figure 3A in *Cancer Res.* 2006 as follows:

- Figure 3A, first row, in *Cancer Res.* 2006, representing the expression of pBad ser 75 in SK MEL 5 cell type with different treatments at different time points
- Figure 3A, eighth row, in *Cancer Res.* 2006, representing pBad ser 99 expression in A375 cell type with the same treatments and at the same time points as the representation of the first row

—Respondent fabricated the bands that were used for Figure 3A, second row, in *Cancer Res.* 2006, representing the expression of pBad ser 99 in SK MEL 5 cell type with different treatments at different time points by using an unrelated image.

—Respondent reused and relabeled the bands to falsely represent AIF expression in mitochondria of the three cell types with different treatments in Figure 6A, the bottom row, in *Cancer Res.* 2006, by:

- Duplicating the bands in the second to fourth lanes to represent mitochondria expression in A375 cell type with Bay 43–9006 (second lane), PD 98059 (third lane), and U0126 (fourth lane) treatments
- duplicating the band for both the fifth and seventh lanes to represent AIF expression in mitochondria of A2058 cell type with no treatment control (fifth lane) and PD 98059 treatment (seventh lane)

—Respondent reused and relabeled the same source bands to falsely represent different experimental results in Figure 3A in *Mol Cancer* 2011 as follows:

- Figure 3A, first four lanes in the middle row of the left panel, in *Mol Cancer* 2011, representing c-myc expression in nucleus of A375 cell type
- Figure 3A, first four lanes in the middle row of the right panel, in *Mol Cancer* 2011, representing c-myc expression in nucleus of SK MEL 5 cell type

—Respondent reused and relabeled the same source bands to falsely represent different experimental results in Figure 5 in *Mol Cancer* 2011 as follows:

- Figure 5, sixth to eighth lanes of the middle row, in *Mol Cancer* 2011, representing BCL–XL expression in A375–GSK cells with DOX
- Figure 5, last three lanes of the middle row, in *Mol Cancer* 2011,

representing BCL–XL expression in SK MEL 5 S9A

—Respondent reused and relabeled the unrelated source bands to falsely represent different experimental results in Figure 5 of *Mol Cancer* 2011 as follows:

- Figure 5, thirteenth to fifteenth lanes of the top row, in *Mol Cancer* 2011, representing BCL2 expression in SK MEL 5 S9A
- Figure 5, thirteenth to fifteenth lanes of the bottom row, in *Mol Cancer* 2011, representing VINCULIN expression in SK MEL 5 S9A

—Respondent reused and relabeled the same source bands to falsely represent different experimental results in Figure 1 in *Mol Cancer* 2013; specifically respondent:

- Reused the bands that were used for Figure 1, fourth to fifth lanes of the second row, in *Mol Cancer* 2013, representing noxa expression in the control group of A498 cell type, to falsely represent noxa expression in the sunitinib resistant group of A498 cells in the same figure, eleventh to twelfth lanes of the second row
- reused the band that was used for Figure 1, eighth lane of the second row, in *Mol Cancer* 2013, representing noxa expression in the third sample of the sunitinib responding group, to falsely represent noxa expression in the fifth sample of the sunitinib responding group in the same figure, tenth lane of the second row

—Respondent reused and relabeled the same source bands to falsely represent different experimental results in Figure 6B in *Mol Cancer* 2013 as follows:

- Figure 6B, first two lanes of the bottom row, in *Mol Cancer* 2013, representing vinculin expression in control group
- Figure 6B, eleventh and twelfth lanes of the bottom row, in *Mol Cancer* 2013, representing vinculin expression in dox + sunitinib group

—Respondent reused and relabeled the same source bands to falsely represent different experimental results in the following three figures:

- Figure 10, second rows of both upper and lower panels, in the 2005 AACR Presentation, representing pSRC–Y416 expression in A2058 (upper) and A375 (lower) cell types
- Figure 4 in *Cancer Res.* 2006 and Figure 6 in the 2005 AACR Presentation, second rows of middle and lower panels, representing Bcl-XL expression in

- A2058 (middle) and SK MEL 5 (lower) cell types
- Respondent reused and relabeled the same source band to falsely represent two different experimental results in Figure 5 in the 2005 AACR Presentation as follows:
- Figure 5, lane 1 of the seventh row, in the 2005 AACR Presentation, representing pBad ser 75 expression at 0 hour in control group
 - Figure 5, lane 2 of the seventh row, in the 2005 AACR Presentation, representing pBad ser 75 expression at 1 hour in control group

Dr. Panka entered into a Voluntary Settlement Agreement and agreed to the following:

(1) Respondent agreed to have his research supervised for a period of three (3) years beginning on November 9, 2020. Respondent agrees that prior to the submission of an application for 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 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) The requirements for Respondent's supervision plan are as follows:

i. A committee of 2–3 senior faculty members at the institution who are familiar with Respondent's field of research, but not including Respondent's supervisor or collaborators, will provide oversight and guidance for a period of three (3) years from the effective date of the Agreement. The committee will review primary data from Respondent's laboratory on a quarterly basis and submit a report to ORI at six (6) month intervals, setting forth the committee meeting dates and Respondent's compliance with appropriate research standards and confirming the integrity of Respondent's research.

ii. The committee will conduct an advance review of any PHS grant applications (including supplements, resubmissions, etc.), manuscripts reporting PHS-funded research submitted for publication, and abstracts. The review will include a discussion with Respondent of the primary data represented in those documents and

will include a certification to ORI that the data presented in the proposed application/publication are supported by the research record.

(3) Respondent agreed that for a period of three (3) years beginning on November 9, 2020, any institution employing him shall submit, in conjunction with each application of 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.

(4) If no supervisory plan is provided to ORI, Respondent agreed to provide certification to ORI at the conclusion of the supervision period that he has not engaged in, applied for, or had his name included on any application, proposal, or other request for PHS funds without prior notification to ORI.

(5) Respondent agreed to exclude himself voluntarily 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 November 9, 2020.

(6) As a condition of the Agreement, Respondent will request that the following papers and conference abstract be corrected or retracted in accordance with 42 CFR 93.407(a)(1) and § 93.411(b):

- *Mol Cancer* 2011 Sep 19;10:115
- *Mol Cancer* 2013 Mar 5;12:17
- 2005 AACR Presentation

Respondent will copy ORI and the Research Integrity Officer at HMS and BIDMC on the correspondence.

Dated: November 20, 2020.

Elisabeth A. Handley,

Director, Office of Research Integrity, Office of the Assistant Secretary for Health.

[FR Doc. 2020–26100 Filed 11–24–20; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review: Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting 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; Small Business: Neuroscience, Biomarkers and Therapeutics.

Date: December 7, 2020.

Time: 1:00 p.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Joseph G. Rudolph, Ph.D., Chief and Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5186, MSC 7844, Bethesda, MD 20892, (301) 408–9098, josephru@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 19, 2020.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–26030 Filed 11–24–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences: Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory General Medical Sciences Council.

The meeting will be open to the public as indicated below, with a short public comment period at the end. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting website (<http://videocast.nih.gov>).

The meeting 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