Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* This guidance document is also available at *https://www.regulations.gov* or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances.* Persons unable to download an electronic copy of ''Process to Request a Review of FDA's Decision Not to Issue Certain Export Certificates for Devices'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 17044 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information. 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. 3501–3521). The collections of information in the following FDA regulations and guidance have been approved by OMB as listed in the following table:

FD&C Act section; 21 CFR part; or guidance	Topic	OMB control No.
FD&C Act sections 801(e) and 802 (21 U.S.C. 382)	Export certificates for FDA regulated products	0910–0498
21 CFR part 820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation.	0910–0073
21 CFR part 807, subparts A through E	Electronic Submission of Medical Device Registration and Listing.	0910–0625
''Center for Devices and Radiological Health Appeals Processes''.	Appeals process	0910–0738

Dated: November 5, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–24717 Filed 11–13–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Standardized Work Plan (SWP) Form for Use With Applications to the Bureau of Health Workforce (BHW) Research and Training Grants and Cooperative Agreements, OMB No. 0906–xxxx–New

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR have been provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this Notice has closed.

DATES: Comments on this ICR should be received no later than December 16, 2019.

ADDRESSES: Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: SWP Form for Use with Applications to BHW Research and Training Grants and Cooperative Agreements, OMB No. 0906–xxxx–NEW

Abstract: BHW requires applicants for training and research grants and cooperative agreements to submit a work plan that describes the timeframes and deliverables required during the grant period of performance to address each of the needs detailed in the Purpose and Need section of the application, as required in the Notice of Funding Opportunity announcement. Applicants are currently able to submit work plans in a non-standardized format.

In order to standardize the data provided by applicants to make informed decisions about funding and assist with monitoring awardee progress, BHW plans to require applicants to complete a SWP form in lieu of submitting a work plan in the applicant's own format. Applicants will use the SWP form when they submit their proposals, and grantees and Project Officers will use the SWP information to assist in monitoring progress once HRSA makes the awards.

A 60-day notice was published in the **Federal Register** on June 19, 2019, Vol. 84, No. 118, pp.28560–28561. There was one public comment and it was thoroughly addressed.

Need and Proposed Use of the Information: The information collected by the SWP form is necessary to standardize and streamline the data used by HRSA in reviewing applications and monitoring awardees. The form will ask applicants to provide a description of the activities or steps the recipient will take to achieve each of the objectives proposed during the entire period of performance. The current variation in formats and data submitted by applicants reduces efficiency in reviewing, awarding, and monitoring each project, so this change will remedy that inefficiency. In addition, seeking OMB approval comports with the regulatory requirement imposed by 45 CFR 75.206(a), Paperwork clearances.

The proposed SWP form will be used to provide information to assess applications for awards including ranking applications as part of the grant review process. BHW will also use the information to assess whether current recipients of grant funding have met statutory and programmatic requirements.

Likely Respondents: Respondents will be applicants to HRSA's research and training programs in BHW.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose

of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Standardized Work Plan	1,000	1	1,000	1	1,000
	1,000		1,000		1,000

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2019–24715 Filed 11–13–19; 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: Findings of research misconduct have been made against Deepti Malhotra, Ph.D. (Respondent), former Doctoral Student and Postdoctoral Fellow, Department of Environmental Health Sciences, Johns Hopkins Bloomberg School of Public Health (JHSPH). Dr. Malhotra engaged in research misconduct in research supported by U.S. Public Health Service (PHS) funds, specifically National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH), grants R01 HL081205, P50 HL084945, P50 HL084948–01, U01 HL105569–03, P50 HL107169–01, R01 HL066554–09, and R03 HL096931–02; National Institute of Environmental Health Sciences (NIEHS), NIH, grants P50 ES015903, P01 ES018176–01, and P30 ES003891–25; National Cancer Institute (NCI), NIH, grant P50 CA058184–18; and National Institute for Research Resources (NCRR), NIH, grant UL1 RR025005–02. The administrative actions, including debarment for a period of four (4) years, were implemented beginning on October 1, 2019, and are detailed below.

FOR FURTHER INFORMATION CONTACT: Elisabeth A. Handley, Interim 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:

Deepti Malhotra, Ph.D., Johns Hopkins Bloomberg School of Public Health: Based on the report of an investigation conducted by JHSPH and analysis conducted by ORI in its oversight review, ORI found that Dr. Deepti Malhotra, former Doctoral Student and Postdoctoral Fellow, Department of Environmental Health Sciences, JHSPH, engaged in research misconduct in research supported by PHS funds, specifically NHLBI, NIH, grants R01 HL081205, P50 HL084945, P50 HL084948–01, U01 HL105569–03, P50 HL107169–01, R01 HL066554–09, and R03 HL096931–02; NIEHS, NIH, grants P50 ES015903, P01 ES018176–01, and P30 ES003891–25; NCI, NIH, grant P50 CA058184–18; and NCRR, NIH, grant UL1 RR025005–02.NCI, NIH, grant R01 CA122737–01A2.

ORI found that Respondent engaged in research misconduct by knowingly, intentionally, and/or recklessly falsifying and/or fabricating data included in the following four (4) published papers and her Ph.D. Thesis:

- *Am J Respir Crit Care Med.* 2008;178(6):592–604 (hereafter referred to as ''*AJRCCM* 2008''). Retracted in: *Am J Respir Crit Care Med.* 2016 Feb 1;193(3):344.
- *Am J Respir Crit Care Med.* 2009;180(12):1196–1207 (hereafter referred to as ''*AJRCCM* 2009''). Retracted in: *Am J Respir Crit Care Med.* 2016 Feb 1;193(3):344.
- *J Clin Invest.* 2011;121(11):4289–4302 (hereafter referred to as ''*JCI* 2011''). Retracted in:

J Clin Invest. 2014 Dec;124(12):5521.

- *PLoS Comput Biol.* 2012;8(7):e1002597 (hereafter referred to as ''*PLoS Comput Biol.* 2012'').
- Malhotra D. ''Transcription Factor Nuclear Factor (Erythroid-Derived 2) Receptor 2 (Nrf2), A Master Regulator of Environmental Stress Response, Is A Modifier Of Chronic Obstructive Pulmonary Disease (COPD).'' A dissertation submitted to the Johns Hopkins University in conformity with the requirements for the degree of Doctor of Philosophy, August 2010 (hereafter referred to as the ''Ph.D. Thesis'').

Respondent knowingly, intentionally, and/or recklessly falsified and/or fabricated Western blot data for protein expression in cultured cell lines and/or alveolar macrophages of patients with chronic obstructive pulmonary disease (COPD) by trimming and manipulating Western blot images to disguise their origin or by reversing negative DNA gel images of the PCR product, reusing and relabeling them to represent Western blot data for unrelated experiments in seventeen (17) figures included in four (4) published papers and twelve (12) figures included in her Ph.D. Thesis. In the absence of original reliable image data, the quantitative data in associated plots, statistical analyses, and related text also are falsified and/or fabricated. Specifically, Respondent falsified and/or fabricated the following figures included in:

- *AJRCCM* **2008**
  - by reusing sets of repeating blot band images from unknown and/or differently labeled film images to falsely create Western Blot panels of:
    - GAPDH in Figure 1C, also included as Figure 2–4B in the Ph.D. Thesis
    - GAPDH, DJ–1 and KEAP1 in Figure 2B, also included as Figure 2–4C in the Ph.D. Thesis
    - GAPDH in Figure 5D, also included as Figure 2–7A in the Ph.D. Thesis
    - DJ–1, NRF2, NQO1, and GAPDH in Figure 6B, also included as Figure 2–8B in the Ph.D. Thesis
- *AJRCCM* **2009**
  - by trimming Western blot panel representing samples from:
    - Human subjects in Figure 4C and in the Ph.D. Thesis, Figure 3–7C, right column, Figure 3–7G, right column, and Figure 3–8A, right column, GAPDH lanes 1–4, and reusing them to represent samples from mice in Figure 3A and in the Ph.D. Thesis, Figure 3–6A
    - normal human subjects in Figures 4C and 5A, left column, and in the Ph.D.