

drug development plan early in development with CDER or CBER, as applicable. The guidance recommends that eligibility criteria for clinical trials of breast cancer drugs allow for inclusion of males. When males have not been included or when inclusion of males is very limited in clinical trials for breast cancer drugs, the guidance includes clinical development recommendations for when no difference in efficacy or safety is anticipated between males and females based on the drug's mechanism of action and for when there is a concern for differential efficacy or safety between males and females.

This guidance finalizes the draft guidance entitled "Male Breast Cancer: Developing Drugs for Treatment" issued on August 27, 2019. FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include the addition of examples of topics for early discussion with FDA and expectations regarding nonclinical studies.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on "Male Breast Cancer: Developing Drugs for Treatment." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

## II. Paperwork Reduction Act of 1995

This guidance refers to previously approved FDA 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 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338; the collections of information in 21 CFR 201.56 and 201.57 have been approved under OMB control number 0910–0572.

## III. Electronic Access

Persons with access to the internet may obtain the guidance at either <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>, or <https://www.regulations.gov>.

*compliance-regulatory-information-biologics/biologics-guidances*, or <https://www.regulations.gov>.

Dated: August 6, 2020.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Health Workforce Connector, OMB No. 0906–0031—Extension

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

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

**DATES:** Comments on this ICR must be received no later than October 13, 2020.

**ADDRESSES:** Submit your comments to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443–1984.

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting information, please include the information request collection title for reference.

*Information Collection Request Title:* Health Workforce Connector, OMB No. 0906–0031—Extension.

*Abstract:* More than just a job search portal, the goal of the Health Workforce Connector is to help connect skilled professionals to communities in need by allowing approved Site Points of

Contact (POCs), including National Health Service Corps (NHSC) and Nurse Corps, to post available opportunities and update site profiles. The Health Workforce Connector provides a central platform to connect participants, including those in both the NHSC and Nurse Corps programs, and facilities that are approved for performance of their NHSC or Nurse Corps service obligation. The Health Workforce Connector has become a resource that engages any health care professional or student interested in providing primary care services in underserved communities and with facilities in need of health care providers. The Health Workforce Connector also allows users to create a profile, search for NHSC and Nurse Corps sites, find job and training opportunities, search for other clinicians who are similarly interested in working with underserved populations, and be searchable by Site POCs. Individuals can use the Health Workforce Connector's search capability with Google Maps.

*Need and Proposed Use of the Information:* Information will be collected from users in the following two ways:

(1) *Account Creation:* Creating an account is optional, but to create an account the user will be required to enter their first name, last name, and email address. Those are the only mandatory fields in the profile account creation process and will be used to send an automated email allowing the user to validate their login credentials. This information will also be used to validate any users who already exist within the Bureau of Health Workforce Management Information Systems Solution (BMISS) database and allow an initial import of existing data at the request of the user.

(2) *Profile Completion:* Users may fill out a profile, but this function will be completely optional and will include fields such as location, discipline, specialty, and languages spoken. The information collected, if 'published' by the user, will allow internal BMISS Site POCs to search for anyone who may be a potential candidate for job opportunities at the site. Users also have the ability to make their profiles searchable by other end users through a security and privacy setting and can make their profiles private at any time. All information collected will be stored within existing secure BMISS databases and will be used internally for report generation on an as-needed basis.

*Likely Respondents:* Potential users will include individuals searching for a health care job opportunity or an NHSC or Nurse Corps health care facility, and

health care facilities searching for potential candidates to fill open health care job opportunities at their sites.

**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
Account Creation .....	15,600	1	15,600	.08	1,248
Complete Profile .....	9,400	1	9,400	1	9,400
Total .....	<sup>1</sup> 15,600	.....	15,600	.....	10,648

<sup>1</sup> The 9,400 respondents who complete their profiles are a subset of the 15,600 respondents who create accounts.

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**Maria G. Button,**

Director, Executive Secretariat.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

#### Findings of Research Misconduct

**AGENCY:** Office of the Secretary, Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** Findings of research misconduct have been made against Zhiwei Wang, M.D. (Respondent), former postdoctoral fellow, Department of Pathology, Karmanos Cancer Institute, Wayne State University (WSU). Dr. Wang 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 P20 CA101936, P30 CA022453, R01 CA075059, R01 CA083695, R01 CA101870, R01 CA109389, R01CA131151, R01 CA132794, and U19 CA113317. The administrative actions, including debarment for a period of ten (10) years,

were implemented beginning on July 21, 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:

*Zhiwei Wang, M.D., Wayne State University:* Based on the report of an investigation conducted by WSU and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Zhiwei Wang, former postdoctoral fellow, Department of Pathology, Karmanos Cancer Institute, WSU, engaged in research misconduct in research supported by PHS funds, specifically NCI, NIH, grants P20 CA101936, P30 CA022453, R01 CA075059, R01 CA083695, R01 CA101870, R01 CA109389, R01CA131151, R01 CA132794, and U19 CA113317.

ORI found that Respondent engaged in research misconduct by knowingly, intentionally, and/or recklessly falsifying data that were included in grant applications R01 CA120008, R01 CA131151, and R01 CA131456 submitted to NCI, NIH; his 2006 Ph.D. dissertation (hereafter referred to as the "Dissertation"); and the following published papers:

- Activated K-Ras and INK4a/Arf deficiency promote aggressiveness of pancreatic cancer by induction of EMT consistent with cancer stem cell phenotype. *J Cell Physiol.* 2013 Mar;228(3):556-62 (hereafter referred to as "*J Cell Physiol.* 2013"). Erratum in: *J Cell Physiol.* 2014 Aug;229(8):1118. Retraction in: *J Cell Physiol.* 2016 Oct;231(10):2304.

- Activated K-ras and INK4a/Arf deficiency cooperate during the development of pancreatic cancer by activation of Notch and NF-κB signaling pathways. *PLoS One* 2011;6(6):e20537 (hereafter referred to as "*PLoS One* 2011"). Erratum in: *PLoS One* 2014;9(6):e101032. Retraction in: *PLoS One.* 2018 Oct 2;13(10):e0205289.

- Down-regulation of Notch-1 is associated with Akt and FoxM1 in inducing cell growth inhibition and apoptosis in prostate cancer cells. *J Cell Biochem.* 2011 Jan;112(1):78-88 (hereafter referred to as "*J Cell Biochem.* 2011"). Retraction in: *J Cell Biochem.* 2016 Aug;117(8):1962.

- Down-regulation of Notch-1 and Jagged-1 inhibits prostate cancer cell growth, migration and invasion, and induces apoptosis via inactivation of Akt, mTOR, and NF-κB signaling pathways. *J Cell Biochem.* 2010 Mar 1;109(4):726-36 (hereafter referred to as "*J Cell Biochem.* 2010"). Retraction in: *J Cell Biochem.* 2016 Aug;117(8):1960.

- TW-37, a small-molecule inhibitor of Bcl-2, inhibits cell growth and invasion in pancreatic cancer. *Int J Cancer* 2008 Aug 15;123(4):958-66 (hereafter referred to as "*Int J Cancer* 2008"). Retraction in: *Int J Cancer.* 2016 Nov 1;139(9):2146.

- Induction of growth arrest and apoptosis in human breast cancer cells by 3,3-diindolylmethane is associated with induction and nuclear localization of p27kip. *Mol Cancer Ther.* 2008 Feb;7(2):341-9 (hereafter referred to as "*Mol Cancer Ther.* 2008").

- Down-regulation of platelet-derived growth factor-D inhibits cell growth and angiogenesis through inactivation of Notch-1 and nuclear factor-κB signaling. *Cancer Res.* 2007 Dec 1; 67(23):11377-85 (hereafter referred to as "*Cancer Res.*