

TABLE 6—CFSAN GUIDANCE

COVID-19 guidance title	CFR cite referenced in COVID-19 guidance	Another guidance title referenced in COVID-19 guidance	OMB control No.
Temporary Policy Regarding Enforcement of 21 CFR Part 118 (the Egg Safety Rule) During the COVID-19 Public Health Emergency.	21 CFR part 118 .....	.....	0910-0660

**IV. Electronic Access**

Persons with access to the internet may obtain COVID-19-related guidances at:

- the FDA web page entitled “COVID-19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders,” available at <https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders>;
- the FDA web page entitled “Search for FDA Guidance Documents,” available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>; or
- <https://www.regulations.gov>.

Dated: May 19, 2020.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2020-11238 Filed 5-22-20; 8:45 am]

**BILLING CODE 4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

[Document Identifier: OS-0937-0198]

**Agency Information Collection Request; 30-Day Public Comment Request**

**AGENCY:** Office of the Secretary, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

**DATES:** Comments on the ICR must be received on or before June 25, 2020.

**ADDRESSES:** Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

**FOR FURTHER INFORMATION CONTACT:** Sherrette Funn, [Sherrette.Funn@hhs.gov](mailto:Sherrette.Funn@hhs.gov) or (202) 795-7714. When submitting comments or requesting information, please include the document identifier 0937-0198-30D and project title for reference.

**SUPPLEMENTARY INFORMATION:** Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (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.

**Title of the Collection: Public Health Service Polices on Research Misconduct (42 CFR part 93)—OMB No. 0937-0198—Extension—Office of Research Integrity.**

*Abstract:* The Office of Research Integrity is requesting an extension on a currently approved collection. The purpose of the Institutional Assurance

and Annual Report on Possible Research Misconduct form PHS-6349 is to provide data on the amount of research misconduct activity occurring in institutions conducting PHS-supported research. The purpose of the Assurance of Compliance by Sub-Award Recipients form PHS-6315 is to establish an assurance of compliance for a sub-awardee institution. Forms PHS 6349 and PHS-6315 are also used to provide an annual assurance that the institution has established and will follow administrative policies and procedures for responding to allegations of research misconduct that comply with the Public Health Service (PHS) Policies on Research Misconduct (42 CFR Part 93). Research misconduct is defined as receipt of an allegation of research misconduct and/or the conduct of an inquiry and/or investigation into such allegations. These data enable the ORI to monitor institutional compliance with the PHS regulation.

*Need and Proposed Use:* The information is needed to fulfill section 493 of the Public Health Service Act (42 U.S.C. 289b), which requires assurances from institutions that apply for financial assistance under the Public Health Service Act for any project or program that involves the conduct of biomedical or behavioral research. In addition, the information is also required to fulfill the assurance and annual reporting requirements of 42 CFR Part 93. ORI uses the information to monitor institutional compliance with the regulation. Lastly, the information may be used to respond to congressional requests for information to prevent misuse of Federal funds and to protect the public interest.

ESTIMATED ANNUALIZED BURDEN HOUR TABLE

Forms (if necessary)	Type of respondent	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
PHS-6349 .....	Awardee Institutions .....	5748	1	12/60	1150
PHS-6315 .....	Sub-Awardee Institutions .....	110	1	5/60	9
Total .....	.....	.....	.....	.....	1159

Dated: May 20, 2020.

**Sherrette A. Funn,**

*Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.*

[FR Doc. 2020-11250 Filed 5-22-20; 8:45 am]

BILLING CODE 4150-31-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 Mr. Logan Fulford (Respondent), who was a graduate research assistant, Cincinnati Children's Hospital Medical Center (CCHMC), and former graduate student, University of Cincinnati (UC). Mr. Fulford engaged in research misconduct in research supported by National Cancer Institute (NCI), National Institutes of Health (NIH), grant R01 CA142724 and National Heart, Lung, and Blood Institute (NHLBI), NIH, grant R01 HL084151. The administrative actions, including supervision for a period of two (2) years, were implemented beginning on May 8, 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:

*Mr. Logan Fulford, Cincinnati Children's Hospital Medical Center:* Based on the report of an investigation conducted by CCHMC and additional analysis conducted by ORI in its oversight review, ORI found that Mr. Logan Fulford, former graduate research assistant, CCHMC, and former graduate student, UC, engaged in research misconduct in research supported by NCI, NIH, grant R01 CA142724 and NHLBI, NIH, grant R01 HL084151.

Respondent neither admits nor denies ORI's findings of research misconduct; the settlement is not an admission of liability on the part of the Respondent. The parties entered into a Voluntary Settlement Agreement (Agreement) to conclude this matter without further expenditure of time, finances, or other resources.

ORI found that Respondent engaged in research misconduct by intentionally,

knowingly, and/or recklessly falsifying data that were included in:

- The transcription factor FOXF1 promotes prostate cancer by stimulating the mitogen-activated protein kinase ERK5. *Science Signaling* 2016 May;9:427 (hereafter referred to as "Science Signaling 2016").

- Foxf1 Deficient Cancer-Associated Fibroblasts Promote Prostate Cancer Progression via Paracrine Wnt11 Signaling. Unpublished manuscript (hereafter referred to as the "unpublished manuscript").

ORI found that Respondent intentionally, knowingly, and/or recklessly falsified immunohistochemistry and western blot data included in *Science Signaling* 2016 and in an unpublished manuscript, by reusing and relabeling images to represent the expression of different proteins and/or different experimental conditions. Specifically:

- In Figure 2C of *Science Signaling* 2016, Respondent reused one immunohistochemistry image, to represent Cle casp-3 expression in Myc-CaP tumors under both Control and FoxF1-OE conditions and used another immunohistochemistry image to represent Cle casp-3 expression in TRAMP tumors under both Control and FoxF1-OE conditions

- in Figure S4E of *Science Signaling* 2016, Respondent reused and relabeled western blot panels to represent the expression of multiple different proteins under different experimental conditions. Specifically:

- Respondent used different exposures of the source blot to represent FOXF1 or WNK1 expression in 22RV1 tumors transfected with scramble RNA or shFOXF1, or pERK5 expression in C4-2B tumors transfected with scramble RNA or shFOXF1

- Respondent used different exposures and size scaling of the source blot to represent MAP3K2 or pERK5 expression in 22RV1 tumors transfected with scramble RNA or shFOXF1 or FOXF1 or WNK1 expression in C4-2B tumors transfected with scramble or shFOXF1

- Respondent used background lightening/darkening and size scaling of the source blot to represent  $\beta$ -ACTIN expression in 22RV1 tumors transfected with scramble or shFOXF1, or Total

ERK5 expression in C4-2B tumors transfected with scramble RNA or shFOXF1

- Respondent used size scaling and rotation of the source blot to represent Total ERK5 in 22RV1 tumors transfected with scramble RNA or shFOXF1, or  $\beta$ -ACTIN expression in C4-2B tumors transfected with scramble RNA or shFOXF1
- in Figure 7C of *Science Signaling* 2016, Respondent reused and relabeled one source western blot panel to represent the expression of different proteins in the presence of FOXF1 overexpression. Specifically:

- different exposures, size scaling, and rotation of the same blot were used to represent  $\beta$ -Actin, pERK5, Total ERK, and MAP3K2 expression in FOXF1-overexpressing Myc-CaP tumors transduced with scramble RNA, shMAP3K2 RNA, shWnk1, or both

- in Figure S3B of *Science Signaling* 2016, Respondent spliced, size scaled, and rotated the source western blot representing expression of Erk5 in TRAMP tumors and represented it as both pERK5 and Total ERK5 expression in TRAMP tumors under both control and FOXF1-OE conditions

- in Figure 3B of the unpublished manuscript, Respondent fabricated the data to falsely represent the upregulation of Wnt11 mRNA in human fibroblasts from prostate cancer samples, compared to those from normal patient samples

- in Figures 3F and S8 of the unpublished manuscript, Respondent reused and relabeled source western blot panels representing Wnt11 expression in HeLa (cervical cancer) to represent Wnt11 expression in MDA-MB-231 fibroblasts (prostate cancer)

As a result of the investigation, *Science Signaling* 2016 was retracted in: *Science Signaling* 2018 Jul;11:541.

Mr. Fulford entered into an Agreement and agreed to the following:

- (1) Respondent agreed to have his research supervised for a period of two (2) years beginning on May 8, 2020. Respondent agreed that prior to the submission of an application for U.S. Public Health Service (PHS) support for a 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