

comment and obtain OMB approval for any information collections recommended in this guidance that are new or that would represent material modifications to those previously approved collections of information found in FDA regulations or guidances.

### III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov>.

Dated: January 11, 2019.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## 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 Srikanth Santhanam, Ph.D. (Respondent), staff scientist in the Division of Gastroenterology, Department of Internal Medicine, Washington University in St. Louis (WUSTL). Dr. Santhanam engaged in research misconduct in research supported by National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institutes of Health (NIH), grants R01 DK109384, R03 DK100737, P30 DK052574, and T32 DK077653; National Institute of Allergy and Infectious Diseases (NIAID), NIH, grants R01 AI126587 and U01 AI1095776; and National Cancer Institute (NCI), NIH, grants R21 CA206039 and P30 CA091842. The administrative actions, including supervision for a period of two (2) years, were implemented beginning on December 14, 2018, and are detailed below.

**FOR FURTHER INFORMATION CONTACT:** Wanda K. Jones, Dr.P.H., Interim Director, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, 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:

*Srikanth Santhanam, Ph.D., Washington University in St. Louis:*

Based on the respondent's voluntary admission and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Srikanth Santhanam, staff scientist in the Division of Gastroenterology, Department of Internal Medicine, WUSTL, engaged in research misconduct in research supported by NIDDK, NIH, grants R01 DK109384, R03 DK100737, P30 DK052574, and T32 DK077653; NIAID, NIH, grants R01 AI126587 and U01 AI1095776; and NCI, NIH, grants R21 CA206039 and P30 CA091842.

In addition to making a voluntary admission, Respondent cooperated fully with WUSTL and ORI and has expressed remorse for his actions.

ORI found that Respondent engaged in research misconduct by falsifying data that were included in a manuscript and a revision submitted to *Cancer Research*, entitled "IDO1 and kynurenine pathway metabolites activate PI3K-Akt signaling in the neoplastic colon epithelium to promote cancer cell proliferation and inhibit apoptosis."

ORI found that Respondent intentionally, knowingly, and/or recklessly falsely labeled figures in both the original submission and the revised submission of the manuscript. Specifically, Respondent falsely reported:

- In Figure 2A and resubmission Figure 3A, that the cytoplasmic and nuclear fraction bands for kynurenine (Kyn) and quinolinic acid (QA) and the nuclear fraction bands for  $\beta$ -Catenin were from a single experiment when they were from unrelated experiments
- in resubmission Figures 4A, 8A, and 8B, the descriptions of Western blot analyses, which he labeled as showing the effect of Kyn and QA on HCT116 cells (Figure 4A), mouse AOM/DSS tumor organoids (Figure 8A) and human FAP tumor organoids (Figure 8B, pPRAS40 only), when in fact he used HT29 cells for each test
- in resubmission Figure 4B, that bands labeled as representing pAKT S473 were actually PRAS40
- in Figure S2C, resubmission Figure 3C, and resubmission Figure S3A, that bands labeled as representing total AKT actually came from an unknown source
- in resubmission Figure 7B, that the bands labeled as representing staurosporine-induced apoptosis were actually the same protein samples used to show TNF- $\alpha$  induced apoptosis in Figure 7A
- in resubmission Figures 3A, 3B, and 4A, that the cell lines used were

between 3 and 10 passages old, when in fact they were passaged more than 10 times.

As a result of the admission, the corresponding author contacted the journal immediately; the manuscript was not reviewed.

Dr. Santhanam entered into a Voluntary Settlement Agreement (Agreement) and voluntarily agreed:

(1) To have his research supervised for a period of two (2) years beginning on December 14, 2018; Respondent agreed that prior to 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 he shall not participate in any PHS-supported research until such a supervision plan 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 two (2) years beginning on December 14, 2018, any institution employing him 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) that if no supervisory plan is provided to ORI, Respondent will 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; and

(4) to exclude himself 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 two (2) years beginning on December 14, 2018.

**Wanda K. Jones,**

*Interim Director, Office of Research Integrity.*

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