TABLE 1—ELIGIBILITY CRITERIA—Continued

Element	Inclusion criteria	Exclusion criteria
Comparators	*KQ1:* Confirmation of diagnosis by a neurosurgeon or neurologist. *KQ2–4:* No surgery, sham surgery, no treatment, or alternative treatments for effectiveness outcomes; no comparator is required for studies reporting adverse events of interest (eligible adverse events will be determined with the help of the TEP).	*KQ 1:* no comparator. For KQ 2–4, Studies without comparator except for studies for an adverse event of interest.
Outcomes	*KQ1:* Diagnostic performance (*e.g.,* diagnostic accuracy measured as concordance with neurosurgeon or neurologist diagnosis); adverse events of the diagnostic procedure; and clinical impact of a correct or incorrect diagnosis such as (*e.g.,* overtreatment due to misdiagnosis, delayed treatment, or undertreatment due to missed diagnosis). *KQ2–4:* Patient health and other patient effects such as leg weakness, leg numbness, leg pain, other pain, gait, walking difficulty, bowel incontinence, bladder incontinence, scoliosis, disability, adverse events, postoperative complications, infection, 30-day complication rate, morbidity, quality of life, or general health status, as well as process measures such as repeat surgery.	Provider satisfaction and frequency of procedures.
Timing	No restrictions regarding the timing or duration of the intervention or the follow up.	N/A.
Setting	Settings compatible with US healthcare settings, no restrictions regarding the clinical setting.	Very low resource countries or conflict zones.
Study Design	*KQ1:* Diagnostic accuracy and diagnostic impact analyses *KQ2–4:* Randomized controlled trials (RCTs), clinical trials without randomization, cohort studies comparing two cohorts, controlled post-only studies, and case-control studies. Experimental single arm trials and observational case series, with or without structured pre- and post-intervention data, need to report on neurological status or bladder or bowel function to be eligible.	Secondary data, but systematic reviews will be retained for reference-mining.
Other limiters	Data published in journal manuscript and trial records	Data reported in abbreviated format (*e.g.,* conference abstracts).

Note: KQ key question, TEP technical expert panel.

Dated: August 29, 2023.

Marquita Cullom,

Associate Director.

[FR Doc. 2023–18984 Filed 8–31–23; 8:45 am]

BILLING CODE 4160–90–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 Surangi (Suranji) Jayawardena, Ph.D. (Respondent), who was an Assistant Professor of Chemistry, University of Alabama in Huntsville (UAH). Respondent engaged in research misconduct in grant applications submitted for U.S. Public Health Service (PHS) funds, specifically R21 AI154256, R21 AI152064, R21 AI149142, and R15 AI146978 submitted to the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH). The administrative actions, including supervision for a period of four (4) years, were implemented beginning on August 18, 2023, and are detailed below.

FOR FURTHER INFORMATION CONTACT: Sheila Garrity, JD, MPH, MBA, 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:

Surangi (Suranji) Jayawardena, Ph.D., University of Alabama in Huntsville: Based on the report of an investigation conducted by UAH, an admission by Respondent, and additional analysis conducted by ORI in its oversight review, ORI found that Surangi (Suranji) Jayawardena, Ph.D., who was an Assistant Professor of Chemistry, UAH, engaged in research misconduct in grant applications submitted for PHS funds, specifically R21 AI154256, R21 AI152064, R21 AI149142, and R15 AI146978 submitted to NIAID, NIH.

ORI found that Respondent engaged in research misconduct by intentionally, knowingly, or recklessly falsifying and/or fabricating data in twelve (12) figure panels in the following four (4) NIH grant applications:

- R21 AI154256, ''Designing artificial glycoforms to inhibit binding of *Clostridioides difficile* flagellin to TLR5,'' submitted to NIAID, NIH, on October 16, 2019, withdrawn on November 5, 2019
- R21 AI152064, ''Multivalent glycoconjugates to inhibit binding of *Clostridioides difficile* flagella to TLR5,'' submitted to NIAID, NIH, on June 14, 2019, administratively withdrawn on November 1, 2021
- R21 AI149142, ''Rapid Low-cost Diagnostics Assay for Mycobacteria through Magnetic Concentration,'' submitted to NIAID, NIH, on February 15, 2019, administratively withdrawn on July 1, 2021
- R15 AI146978, ''BACTERIA HOMING–IN GLYCAN SENSING,'' submitted to NIAID, NIH, on October 25, 2018, administratively withdrawn on March 1, 2021

Specifically, ORI found that Respondent intentionally, knowingly, or recklessly falsified and/or fabricated the following image data by reusing data from the same source and falsely relabeling the data as representing different experimental conditions with antibiotic particles or bacteria:

• Transmission electron microscopy (TEM) images of:

—(left) NeuNAc-AuNPs and (middle) enlarged image showing binding of NeuNAc-AuNP binding to flagella and (right) Man-AuNPs in Figure 1b of R21 AI152064

—(left) NeuNAc-[60]fullerene and (middle) enlarged image showing binding of NeuNAc-[60]fullerene binding to flagella and (right) Man-[60]fullerene in Figure 1e of R21 AI154256

• photos of the formation of magnetic precipitate in a microcentrifuge tube representing:

—CSL3-magSNPs binding *Pseudomonas aeruginosa* in Figure 3a of R15 AI146978

—ConA-mag beads binding *Mycobacterium bovis* in Figure 2A of R21 AI149142

• photos of the lack of magnetic precipitate in a microcentrifuge tube representing CSL3 magSNPs remaining in solution in the presence of:

—*Staphylococcus aureus* in Figure 3b of R15 AI146978

—*Mycobacteria smegmatis* in Figure 3d of R15 AI146978

Additionally, Respondent reported the following images that were falsely relabeled to represent different bacterial experimental conditions:

• photos of the formation of magnetic precipitate in a microcentrifuge tube representing:

—lectin or antibody treated magnetic beads binding *Mycobacterium bovis* in Figures 2A, 2B, and 2C of R21 AI149142

Respondent entered into a Voluntary Settlement Agreement (Agreement) and voluntarily agreed to the following:

(1) Respondent will have her research supervised for a period of four (4) years beginning on August 18, 2023 (the ''Supervision Period''). 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 in PHS-supported research, Respondent will submit a plan for supervision of Respondent's duties to ORI for approval. The supervision plan must be designed to ensure the integrity of Respondent's research. Respondent will not participate in any PHS-supported research until such a supervision plan is approved by ORI. Respondent will comply 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 four (4) 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 each application for PHS funds, or report, manuscript, or abstract involving PHS-supported research in which Respondent is involved. 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, report, manuscript, or abstract are supported by the research record.

(3) During the Supervision Period, Respondent will ensure that any institution employing her submits, 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 and not plagiarized in the application, report, manuscript, or abstract.

(4) If no supervision plan is provided to ORI, Respondent will provide certification to ORI at the conclusion of the Supervision Period that her participation was not proposed on a research project for which an application for PHS support was submitted and that she has not participated in any capacity in PHS-supported research.

(5) During the Supervision Period, Respondent will exclude herself voluntarily from serving in any advisory or consultant capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee.

Dated: August 29, 2023.

Sheila Garrity,

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

[FR Doc. 2023–18954 Filed 8–31–23; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; Notice of Closed Meeting

Pursuant to section 1009 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: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel NIDCD Institutional Training Grant Review Meeting.

Date: September 27, 2023.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Kausik Ray, Ph.D., Scientific Review Officer, National Institute on Deafness and Other Communication Disorders, National Institutes of Health, 6001 Executive Blvd., Rockville, MD 20852, 301–402–3587, *rayk@nidcd.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.173, Biological Research Related to Deafness and Communicative Disorders, National Institutes of Health, HHS)

Dated: August 28, 2023.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–18932 Filed 8–31–23; 8:45 am]

BILLING CODE 4140–01–P