

Human Research Protections (SACHRP) will hold a meeting that will be open to the public. Information about SACHRP and the full meeting agenda will be posted on the SACHRP website at: <http://www.dhhs.gov/ohrp/sachrp-committee/meetings/index.html>.

DATES: The meeting will be held on Tuesday, March 13, 2018, from 8:30 a.m. until 5:00 p.m., and Wednesday, March 14, 2018, from 8:30 a.m. until 4:00 p.m.

ADDRESSES: Fishers Lane Conference Center, Terrace Level, 5635 Fishers Lane, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Julia Gorey, J.D., Executive Director, SACHRP; U.S. Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, Maryland 20852; telephone: 240-453-8141; fax: 240-453-6909; email address: SACHRP@hhs.gov.

SUPPLEMENTARY INFORMATION: Under the authority of 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, SACHRP was established to provide expert advice and recommendations to the Secretary of Health and Human Services (HHS), through the Assistant Secretary for Health, on issues and topics pertaining to or associated with the protection of human research subjects.

The Subpart A Subcommittee (SAS) was established by SACHRP in October 2006 and is charged with developing recommendations for consideration by SACHRP regarding the application of subpart A of 45 CFR part 46 in the current research environment.

The Subcommittee on Harmonization (SOH) was established by SACHRP at its July 2009 meeting and charged with identifying and prioritizing areas in which regulations and/or guidelines for human subjects research adopted by various agencies or offices within HHS would benefit from harmonization, consistency, clarity, simplification and/or coordination.

The SACHRP meeting will open to the public at 8:30 a.m., on Tuesday, March 13, 2018, followed by opening remarks from Dr. Jerry Menikoff, Director of the Office for Human Research Protections and Dr. Stephen Rosenfeld, SACHRP Chair.

The SAS and SOH subcommittees will present their recommendations regarding the description of “key information,” as required by the revised Common Rule’s § 46.116(a)(5)(i). This will be followed by a discussion of SOH recommendations on the research use of repositories and registries under various consent models, under both the current and the revised Common Rule. The

Tuesday, March 13, meeting will adjourn at approximately 5:00 p.m.

The Wednesday, March 14, meeting will begin at 8:30 a.m. The SOH will present and discuss recommendations on the European Union’s General Data Protection Regulation and its impact on U.S. human subjects research. Modifications to the previous day’s work will be discussed and finalized. The meeting will adjourn at approximately 4:00 p.m.

Time for public comment sessions will be allotted both days. On-site registration is required for participation in the live public comment session. Note that public comment must be relevant to issues currently being addressed by the SACHRP. Individuals submitting written statements as public comment should email or fax their comments to SACHRP at SACHRP@hhs.gov at least five business days prior to the meeting.

Public attendance at the meeting is limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the designated SACHRP point of contact at the address/phone number listed above at least one week prior to the meeting.

Dated: February 16, 2018.

Julia G. Gorey,

Executive Director, Secretary’s Advisory Committee on Human Research Protections.

[FR Doc. 2018-03768 Filed 2-22-18; 8:45 am]

BILLING CODE 4150-36-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 on the part of Colleen T. Skau, Ph.D., former postdoctoral fellow in the Cell Biology and Physiology Center, National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH). Dr. Skau engaged in research misconduct in research supported by NHLBI, NIH. The administrative actions, including three (3) years of supervision, were implemented beginning on January 25, 2018, and are detailed below.

FOR FURTHER INFORMATION CONTACT: Wanda K. Jones, Ph.D., Interim Director, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (240) 453-8200.

SUPPLEMENTARY INFORMATION:

Colleen T. Skau, Ph.D., National Institutes of Health: Based on Respondent’s admission, an assessment conducted by NIH, and analysis conducted by ORI in its oversight review, ORI found that Dr. Colleen T. Skau, former postdoctoral fellow in the Cell Biology and Physiology Center, NHLBI, NIH, engaged in research misconduct in research supported by NHLBI, NIH.

ORI found that Respondent engaged in research misconduct by intentionally, knowingly, or recklessly reporting falsified and/or fabricated data and/or falsifying and/or fabricating data in the following two (2) papers:

- *Cell* 167(6):1571–1585, 2016 (hereafter referred to as “Paper 1”)
- *Proceedings of the National Academy of Sciences* 112(19):E2447–E2456, 2015 (hereafter referred to as “Paper 2”)

ORI found that Respondent engaged in research misconduct by intentional, knowing, or reckless falsification and/or fabrication of the research record by selectively reporting by inappropriate inclusion/omission or alteration of data points in ten (10) figures and falsely reporting the statistical significance based on falsified data in ten (10) figures across the two (2) papers and supplementary material. Specifically, ORI found that:

- In Paper 1, Respondent falsified and/or fabricated the research record in:
 - Figure 3B, by selectively omitting/including data points in the Rescue condition
 - Figure 5B, by reporting a significant difference between conditions by performing statistical calculations based on fabricated primary data
 - Figure 5C (bottom), by selectively omitting images and conditions from the analysis
 - Figure 6I (bottom left), by reporting data from the same data set as Figure 6B (top)
 - Figure 55B, by reporting statistical significance despite performing a T test calculation that returned an insignificant p-value
 - Figure 7F, by reporting that error bars represented standard deviation, when they actually represented standard error of the mean (SEM.)
 - Figure S4D, by performing different normalizing calculations in the Rescue condition than performed in other conditions and by omitting three data points from the Rescue conditions calculated average
- In Paper 2, Respondent falsified and/or fabricated the research record in:

- Figure 1E, by selectively omitting data points from the analysis
- Figure 2A, by selectively omitting data points from the analysis
- Figure 2C (left and right), by changing selected raw measurements by multiplying with a fixed value to make the data consistent with data collected in other experiments
- Figure 5B, by selectively including and omitting data points from the analysis
- Figure 5C, by selectively including and omitting data points from the analysis
- Figure 7A (right), by reporting that error bars represented standard deviation, when they actually represented standard error of the mean (SEM.)

ORI found that Respondent engaged in research misconduct by intentionally, knowingly, or recklessly falsely claiming in the methods and results to have performed validation of deletion/re-expression of FMNR2 levels in genetically modified B16 cell lines when that genetic modification was not validated for data reported in Figures 7 and 7S of Paper 1.

ORI found that Respondent engaged in research misconduct by intentionally, knowingly, or recklessly falsely reporting a larger number of data points than actually were collected in fourteen (14) figures across the two (2) papers and supplementary materials. Specifically:

- In Paper 1, Respondent falsified and/or fabricated the reported data in:
 - Figure 2B (top), by reporting ten (10) cells per condition when nine (9) Knock Down (KD) and eight (8) Rescue were included in the analysis
 - Figure 2B (middle), by reporting ten (10) cells per condition when eight (8) Rescue were included in the analysis
 - Figure 3B (top), by reporting twenty-five (25) cells per condition when nineteen (19) Control, nineteen (19) KD, and fourteen (14) Rescue were included in the analysis
 - Figure 3B (bottom), by reporting twenty-five (25) cells per condition when twenty-four (24) Control and twenty-three (23) Rescue were included in the analysis
 - Figure 5A, by reporting to have examined fifty (50) cells per condition, when only twenty-three (23), twenty-three (23), and twelve (12) for the 2mg/mL conditions (Control, KD, and Rescue, respectively) and twenty-five (25), twenty (20), and nine (9) for the 3mg/mL conditions (Control, KD, and Rescue, respectively) were recorded

- Figure 6D, by reporting ten (10) cells per condition when only eight (8) Control were recorded
- Figure 7D, by reporting four (4) mice for each of two (2) independent clones (8 total) for each condition when only four (4) Vector+GFP, four (4) WT, and two (2) B16 conditions were examined
- Figure S2E (top), by reporting to have measured two hundred fifty (250) Focal Adhesions per condition, when only fifty-six (56) measurements were recorded for the Leading Edge Adhesions (LEA) analysis
- Figure S2E (3rd row left and 4th row left), by reporting twenty-five (25) cells per condition when only ten (10) cells were recorded
- Figure S4C, by reporting ten (10) cells per condition when only five (5) cells were recorded
- Figure S5B, by reporting ten (10) cells per condition when only seven (7) and six (6) cells were recorded for Control and KD respectively
- Figure S6E, by reporting twenty-five (25) cells per condition when only twenty-four (24), eighteen (18), and sixteen (16) cells were recorded for Control (48hr), KD (24hr), and KD (48hr) respectively

- In Paper 2, Respondent falsified and/or fabricated the reported data in:
 - Figure 1E (top), by reporting six (6) cells per condition when only three (3) were recorded in Tropomyosin (Tpm) analysis
 - Figure 2C (middle and right), by reporting twenty (20) cells per condition when only sixteen (16), sixteen (16), and five (5) cells were recorded for Control, KD, and Rescue respectively
 - Figure 3A (right), by reporting the data from one of four analyses in the KD condition as the average of five
 - Figure 3C (right), by reporting examination of ten (10) stress fibers per condition when only three (3), four (4), and seven (7) cells were recorded for Control, KD, and Rescue respectively
 - Figure 5B, overstating the number of adhesions examined
 - Figure 5C, overstating the number of cells examined in all conditions
 - Figure 7D (right), by reporting examination of ten (10) cells per condition when only five (5), four (4), and five (5) cells were recorded for Control, KD, and Rescue respectively
- ORI found that Respondent engaged in research misconduct by intentionally, knowingly, or recklessly fabricating results and/or falsely labelling experimental results that arose from alternate experimental conditions/

experiments in seven (7) figures across the two (2) papers and supplementary materials. Specifically:

- In Paper 1, Respondent falsified and/or fabricated the record in:
 - Figure 5B (top right), by reporting results of 8 and 12 um pore migration, which did not originate from experimental observations
 - Figure 5B (bottom left), by reporting results for the Rescue condition, which did not originate from experimental observations
 - Figure 5B (left), by using selected regions from the same original image to represent both the control (top) and rescue conditions (bottom)
 - Figure 5C (bottom), by reporting data derived from 2.5um channels as originating from 3.5um channels
 - Figure 6B (top), by reporting results for the “Glass” condition (all treatments) and rescue treatment (both conditions) that did not originate from experimental observations
 - Figure 6B (bottom), by reporting results for the 8um pore condition that did not originate from experimental observations
 - Figure 6E, by reporting results for the ATRi and ATMi treatments (Control and KD conditions) and DMSO control (Rescue condition) that did not originate from experimental observations and reporting results as originating from DMSO (Control and KD conditions) controls that had originated from a different treatment
 - Figure 6G, by reporting results for the “No Drug” conditions that did not originate from experimental observations
 - Figure 6I, by reporting results in all conditions that originated in part from the same experimental dataset reported in Figure 6B (top)
 - Figure S4D, by reporting results that did not originate from experimental observations for the KD condition
 - Figure S6C (right), by shifting selected data points in the KD condition from their original time points to different time points
 - Figure S7A, by using bands to represent FMN2 expression in six separate conditions, which originated from different molecular weight regions in three lanes on the original Western blot, and by representing absence of FMN2 expression in two conditions (CRISPR1 and CRISPR2) by reporting absence of bands in lanes in which no protein had been loaded
 - Figure S7F (rightmost), by selecting single data points from different treatments and reporting them as means and standard deviations for all of the treatments

- In Paper 2, Respondent falsified and/or fabricated the record in:
 - Figure 2A (top), by reporting results for the Rescue condition that did not originate from experimental observations
 - Figure 3C (right), by reporting results for the Rescue condition that did not originate from experimental observations

Dr. Skau entered into a Voluntary Settlement Agreement and voluntarily agreed, beginning on January 25, 2018:

(1) To have her research supervised for a period of three (3) years; Respondent agreed to ensure that 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 on PHS-supported research, the institution employing her must submit a plan for supervision of Respondent's duties to ORI for approval; the plan for supervision must be designed to ensure the scientific integrity of Respondent's research contribution; Respondent agreed that she will not participate in any PHS-supported research until a plan for supervision is submitted and approved by ORI; Respondent agreed to maintain responsibility for compliance with the agreed upon plan for supervision.

(2) that for a period of three (3) years, any institution employing her must 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) if no supervisory plan is provided to ORI, to provide certification to ORI on annual basis that she has not engaged in, applied for, or had her name included on any application, proposal, or other request for PHS funds without prior notification to ORI;

(4) to exclude herself voluntarily 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 three (3) years; and

(5) to the correction or retraction of:

- *Cell* 167(6):1571–1585, 2016

- *Proceedings of the National Academy of Sciences* 112(19):E2447–E2456, 2015

Wanda K. Jones,

Interim Director, Office of Research Integrity.

[FR Doc. 2018–03766 Filed 2–22–18; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings 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: Center for Scientific Review Special Emphasis Panel; Small Business: Cancer Drug Development and Therapeutics.

Date: March 19–20, 2018.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW, Washington, DC 20015.

Contact Person: Lilia Topol, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6192, MSC 7804, Bethesda, MD 20892 301–451–0131, ltopol@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Disease Prevention and Management, Risk Reduction and Health Behavior Change.

Date: March 19–20, 2018.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Westin Grand, 2350 M Street NW, Washington, DC 20037.

Contact Person: Michael John McQuestion, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3114, Bethesda, MD 20892, 301–480–1276, mike.mcquestion@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR17–316; Biomedical Technology Research Resource (P41).

Date: March 19, 2018.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW, Washington, DC 20015.

Contact Person: Mark Caprara, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5156, MSC 7844, Bethesda, MD 20892, 301–435–1042, caprarang@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Topics in Bacterial Pathogenesis.

Date: March 19, 2018.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Richard G. Kostriken, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3192, MSC 7808, Bethesda, MD 20892, 240–519–7808, kostrikr@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business Hematology.

Date: March 19–20, 2018.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Bukhtiar H. Shah, DVM, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4120, MSC 7802, Bethesda, MD 20892, 301–806–7314, shahb@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: February 16, 2018.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–03702 Filed 2–22–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Center for Scientific Review Advisory Council.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to