From: (b)(6); (b)(7)(C)
To: HHS/OASH)
Cc: Runko, Alexander (HHS/OASH); Pollack, Ann
Subject: Letter from VCR Wakimoto
Date: Friday, September 9, 2022 5:33:08 PM
Attachments: (b)(6) o ORI Sept 9 2022.pdf

Dear (b)(6); (b)(7)(C)

Hope this email finds you well. Enclosed please find a letter from VC Wakimoto. If you have any questions, feel free to reach out to Associate Vice Chancellor Ann Pollack.

Best regards

(b)(6); (b)(7)(C)

UCLA Office of Research & Creative Activities
Email: (b)(6); (b)(7)(C) @conet.ucla.edu |
Web: https://research.ucla.edu/

UCLA Research & Creative Activities

Roger H. Wakimoto, Ph.D.
2148 Murphy Hall
Mail Code: (b)(6); (b)(7)(C)
Phone: (310)
Email:
(b)(6); (b)(7)(C)

September 9, 2022

VIA EMAIL

(b)(6); (b)(7)(C)
Division of Investigative Oversight
Office of Research Integrity
U.S. Department of Health and Human Services
Email: (b)(6); (b)(7)(C)

Re: DIO 7163

Dear (b)(6); (b)(7)(C)

I am writing again to update our request regarding the report to ORI that led to factual errors in the August 5, 2022 *Federal Register* notice pertaining to the findings of research misconduct against Janina Jiang, M.D., Ph.D. I initially wrote to you on August 16, 2022, to follow up on your telephone conversations with Ann Pollack, UCLA Associate Vice Chancellor – Research.

The *Federal Register* notice erroneously states that a figure was incorporated into a proposal that UCLA submitted to the National Institutes of Health (NIH) to support UL1 TR000124, the UCLA Clinical and Translational Science Institute (CTSI), for the period June 1, 2011- August 31, 2016. This statement is false. The figure was not part of UCLA CTSI UL1 TR000124 and was **not** submitted to the NIH.

Dr. Jiang did **not** receive any funding from UCLA CTSI UL1 TR000124 at any time. A review of all UCLA CTSI UL1 TR000124 documents, which includes the original grant submission and all progress reports and records reveals no evidence whatsoever of any support or data related to Dr. Jiang. The *Federal Register* notice states that the ORI found that Dr. Jiang "engaged in research misconduct by knowingly and recklessly falsifying and/or fabricating flow cytometry data" that was included in the UCLA CTSI grant UL1 TR000124. This data was **not** incorporated into the UCLA CTSI application for funding of UL1 TR000124.

I recently learned that the clarification previously provided was incorrect. When I wrote to you on August 16th, I had understood that CTSI funds provided by NIH had been used to support the project. But I have since learned that the seed grant that included Dr. Jiang's work was funded by unrestricted (b)(6); (b)(7)(C)

(b)(6); (b)(7)(C) through an internal funding program (b)(6); (b)(7)(C). The proposal was **not** funded by the UCLA CTSI grant UL1 TR000124 nor any other UCLA CTSI funding. ORI, therefore, has no jurisdiction over the first allegation.

The erroneous initial information about the source of funding for Dr. Jiang's research was based on information provided to the Inquiry and Investigation Committees during their work. This erroneous information was reflected in the reports that UCLA provided to ORI as well as in the clarification provided by Associate Vice Chancellor Pollack. After the *Federal Register* notice was published, another source directly involved with primary documentation, reviewed detailed records of UCLA CTSI funding expenditures, contacted me and provided additional evidence that reflects the true source of funding used to support work for this internally supported proposal. A review of all UCLA CTSI UL1 TR000124 documents, which includes the original grant submission and all progress reports and records, substantiates that no NIH UCLA CTSI UL1 TR000124 funding was awarded to Dr. Jiang.

Please let me know whether this letter is sufficient or whether UCLA needs to provide your office with an updated investigation report reflecting this corrected information. This current information underscores the urgent need for ORI to correct the *Federal Register* notice. The *Federal Register* provides the public with reliable information about government activities. Once published in the *Federal Register*, that information is publicly available. Anyone with access to the internet can find this information, and it will remain available indefinitely. Information in the *Federal Register* is understandably viewed as authoritative and thus relied on by a broad range of individuals and organizations. *See, e.g.*, 44 U.S.C. § 1507 ("[P]ublication in the Federal Register of a document creates a rebuttable presumption— (1) that it was duly issued, prescribed, or promulgated ....").

(b)(6); (b)(7)(C) rectify the record by publishing a correction in the *Federal Register* indicating that **no NIH** funds were used in support of the proposal in which the falsified/fabricated figure related to allegation one appeared. (b)(6); (b)(7)(C)

(b)(6); (b)(7)(C) We respectfully request that ORI issue a correction to the official record in the Federal *Register* that reflects a complete and accurate picture of what occurred in this case.

It is urgent that the correct factual information be immediately and accurately presented in the Federal Register.

If you have questions, please contact Associate Vice Chancellor Ann Pollack at (b)(6); (b)(7)(C)

Sincerely,

(b)(6); (b)(7)(C)

Roger M. Wakimoto
Vice Chancellor for Research and Creative Activities
Research Integrity Officer

cc: DIO Director Alex Runko, Office of Research Integrity
Associate Vice Chancellor-Research Ann Pollack

From: (b)(6); (HHS/OASH)
To: Runko, Alexander (HHS/OASH); (b)(6); HHS/OASH)
Subject: Jiang Correction Notice
Date: Thursday, September 22, 2022 11:12:54 AM
Attachments: 2022-20070 Jiang Correction Notice.pdf

Hi Alex (b)(6); (b)(7)(C)

In case you didn't see this on the *Fed. Reg*. site while I was gone, here's the published correction notice for Jiang.

Thanks,

(b)(6); (b)(7)(C)

Division of Investigative Oversight

Office of Research Integrity

Email: (b)(6); (b)(7)(C)

Desk: (b)(6); (b)(7)(C)

DATES: Comments on the ICR must be received on or before November 15, 2022.

ADDRESSES: Submit your comments to *Sherrette.Funn@hhs.gov* or by calling (202) 795–7714.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0990–New–60D and project title for reference, to Sherrette A. Funn, email: *Sherrette.Funn@hhs.gov,* or call (202) 795–7714 the Reports Clearance Officer.

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: Data Management Standard Operating Procedures Survey.

Type of Collection: New.

OMB No.: 0990–New.

Abstract: The Office of the Assistant Secretary for Health, Office of Research Integrity is requesting a new approval from the Office of Management and Budget of the Data Management Standard Operating Procedures Survey. Information from respondents to the survey will be used to develop a Data Management Standard Operating Procedures toolkit that will be disseminated to researchers, research administrators, and research institutions to implement. In addition, other products will be developed to disseminate survey results and findings to include, social media posts, YouTube video, webinar, and summary report for the research community.

Likely Respondents: Biostatisticians and Bioscience Researchers.

ANNUALIZED BURDEN HOUR TABLE

Form name	Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Data Management Standard Operating Procedures Survey.	Biostatisticians and Bioscience Researchers.	1,200	1	45/60	900
Total					900

Sherrette A. Funn,

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

[FR Doc. 2022–20115 Filed 9–15–22; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Research Misconduct; Correction

AGENCY: Office of the Secretary, HHS.

ACTION: Correction of notice.

SUMMARY: This document corrects errors that appeared in the notice published in the August 5, 2022, **Federal Register** entitled ''Findings of Research Misconduct.''

Applicability Date: The correction notice is applicable for the Findings of Research Misconduct notice published on August 5, 2022.

FOR FURTHER INFORMATION CONTACT: Dr. Alexander Runko or Ms. Karen Gorirossi at 240–453–8800.

SUPPLEMENTARY INFORMATION:

I. Background

In FR Doc. 2022–16867 of August 5, 2022 (87 FR 48034–48036), there were errors involving National Institutes of Health (NIH) grant application UL1 TR000124 affecting six paragraphs on page 48035. The errors are identified and corrected in the Correction of Errors section below.

II. Correction of Errors

Due to additional information provided by the institution to the Office of Research Integrity, it was determined that NIH grant application UL1 TR000124 did not fund or contain falsified/fabricated data; therefore, this grant application has been removed from the findings of research misconduct reported in FR Doc. 2022–16867. Thus, in FR Doc. 2022–16867 of August 5, 2022 (87 FR 48034–48036), make the following corrections:

1. On page 48035, first column, in FR Doc. 2022–16867, first paragraph, lines 9–12, remove ''UL1 TR000124 submitted to the National Center for Advancing Translational Sciences (NCATS), NIH.''

2. On page 48035, first column, in FR Doc. 2022–16867, fourth paragraph, lines 14–15, remove ''UL TR000124 submitted to NCATS, NIH.''

3. On page 48035, first column, in FR Doc. 2022–16867, fifth paragraph, lines 5–6, change ''eleven (11) grant applications'' to ''ten (10) grant applications.''

4. On page 48035, first column, in FR Doc. 2022–16867, seventh paragraph, lines 1–2, and second column, in FR Doc. 2022–16867, first paragraph, lines 1–3, remove ''UL1 TR000124, 'UCLA Clinical and Translational Science Institute,' submitted to NCATS, NIH, Awarded Project Dates: June 1, 2011–August 31, 2016.''

5. On page 48035, second column, in FR Doc. 2022–16867, thirteenth paragraph, line 1, remove ''Figure 6 of UL1 TR000124.''

Dated: September 13, 2022.

Wanda K. Jones,

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

[FR Doc. 2022–20070 Filed 9–15–22; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Tick-Borne Disease Working Group

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: As required by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that the Tick-Borne Disease Working Group (TBDWG) will hold a meeting. The meeting will be open to the public via webcast. For this meeting, the TBDWG will review and vote upon the

From: (b)(6); (b)(7)(C) HHS/OASH)
To: S/OASH)
Cc: (HHS/OASH); Runko, Alexander (HHS/OASH)
Subject: Case Summary for ORI 2022-12 for ORI website
Date: Wednesday, July 27, 2022 11:53:05 AM
Attachments: ORI 2022-12 case summary.docx

Hi (b)(6); (b)(7)(C)

Attached is the case summary for 2022-12 (misconduct finding). Please post on the ORI website next Tuesday, August 2.

(b)(6); (b)(7)(C)

Thanks!

(b)(6); (b)(7)(C)

Division of Investigative Oversight

Office of Research Integrity

Email: (b)(6); (b)(7)(C)

Desk: (b)(6); (b)(7)(C)

2022-12

Janina Jiang, M.D., Ph.D., University of California, Los Angeles: Based on the report of an investigation conducted by the University of California, Los Angeles (UCLA) and additional analysis conducted by the Office of Research Integrity (ORI) in its oversight review, ORI found that Janina Jiang, M.D., Ph.D. (Respondent), former Assistant Researcher in the Department of Pathology & Laboratory Medicine at the David Geffen School of Medicine, University of California, Los Angeles (UCLA) engaged in research misconduct in research included in grant applications submitted for U.S. Public Health Service (PHS) funds, specifically R43 CA228629-01 submitted to the National Cancer Institute (NCI), National Institutes of Health (NIH), UL1 TR000124 submitted to the National Center for Advancing Translational Sciences (NCATS), NIH, and P01 AI131294-01, R01 AI126914-01, R21 AI131013-01, R21 AI131451-01, R21 AI131451-01A1, R21 AI142068-01, R43 AI136224-01, R44 AI126960-01, and R44 AI128983-01 submitted to the National Institute of Allergy and Infectious Diseases (NIAID), NIH.

ORI found that Respondent engaged in research misconduct by knowingly and recklessly falsifying and/or fabricating flow cytometry data that were included in the following eleven (11) grant applications submitted for PHS funds:

- R43 CA228629-01, "CTL Based Therapeutic Vaccine to Prevent or Interrupt HPV Mediated Oncogenesis," submitted to NCI, NIH, Awarded Project Dates: September 18, 2018-February 29, 2020.

- UL1 TR000124, "UCLA Clinical and Translational Science Institute," submitted to NCATS, NIH, Awarded Project Dates: June 1, 2011-August 31, 2016.

- P01 AI131294-01, "Defining Factors Controlling HIV Rebound," submitted to NIAID, NIH, Awarded Project Dates: August 10, 2017-July 31, 2022.

- R01 AI126914-01, "A Recombinant Human Vault CTL-Based HIV Vaccine Component," submitted to NIAID, NIH, on December 23, 2015.

- R21 AI131013-01, "A Novel Cellular Immune Zika Vaccine," submitted to NIAID, NIH, on June 14, 2016.

- R21 AI131451-01, "A Novel Therapeutic Vaccine for HPV Oncogenesis," submitted to NIAID, NIH, on June 14, 2016.

- R21 AI131451-01A1, "A Novel Therapeutic Vaccine for HPV Oncogenesis," submitted to NIAID, NIH, on June 13, 2017.

- R21 AI142068-01, "A Novel Therapeutic Vaccine for HPV Oncogenesis," submitted to NIAID, NIH, on February 12, 2018.

- R43 AI136224-01, "Development of A Novel Pan-Serovar Vaccine for Chlamydia," submitted to NIAID, NIH, on April 5, 2017.

- R44 AI126960-01, "Novel Pan-Serovar Vaccine for Chlamydia," submitted to NIAID, NIH, on January 4, 2016.

- R44 AI128983-01, "Design of a Novel CTL Retargeting Therapeutic HIV Vaccine," submitted to NIAID, NIH, on April 2, 2016.

ORI found that Respondent knowingly and recklessly falsified and/or fabricated flow cytometry data to represent interferon-γ (IFN-γ) expression in immune cells of mice administered with human recombinant vaults such that the represented data were incompatible with the raw experimental data. Specifically, Respondent falsified and/or fabricated flow cytometry data to represent:

- IFN-γ expression in the immune cells of mice injected subcutaneously or intranasally with human recombinant vaults containing HIV Gag peptides such that the vaccinated arm of the experiment showed antigen-specific T-cell responses in:

  - Figure 6 of UL1 TR000124
  - Figure 2 of R43 CA228629-01
  - Figure 8 of R21 AI131451-01
  - Figure 9 of R21 AI131451-01A1
  - Figure 9 of R44 AI126960-01
  - Figure 3 of R43 AI136224-01
  - Figure 9 of R21 AI131013-01
  - Figure 7 of R01 AI126914-01
  - Figure 7 of R44 AI128983-01
  - Figures 8A and 8B of R21 AI142068-01

- increased IFN-γ expression in the immune cells of mice injected with human recombinant vaults containing HPV peptides in Figure 3 of R43 CA228629-01

- dose-dependent increase in IFN-γ expression in the immune cells of mice injected with human recombinant vaults containing HIV Gag peptides in Figure 8 of P01 AI131294-01 and Figure 8C of R21 AI142068-01

- IFN-γ expression in the immune cells of mice administered intranasally with human recombinant vaults containing HPV peptides in Figure 10 of R21 AI131451-01A1 and Figure 10 of R21 AI142068-01

- IFN-γ expression in the immune cells of mice administered orally with human recombinant vaults containing HIV Gag peptides in Figure 11 of R21 AI131451-01A1 and Figure 9 of R21 AI142068-01

- IFN-γ expression in the immune cells of mice immunized subcutaneously with increasing doses of human recombinant vaults containing HIV Gag-1 spanning peptides in Figure 14 of R01 AI126914-01 and Figure 13 of R44 AI128983-01

Dr. Jiang entered into a Voluntary Settlement Agreement (Agreement) and voluntarily agreed to the following:

(1) Respondent will have her research supervised for a period of three (3) years beginning on July 22, 2022 (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 two 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 three (3) years from the effective date of this Agreement. The committee will review Respondent's primary data 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 Respondent's research. 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 Respondent's 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.

A *Federal Register* notice (FRN) has been submitted to the *Federal Register* for this case. When the FRN is published in the *Federal Register*, the link will be provided here.

In accordance with Freedom of Information Act (FOIA), I am requesting copies of correspondence to or from the following people, whether primary or copied:

- Dr. Wanda Jones. Acting Director, ORI
- Alexander Runko, Director, Division of Investigative Oversight, ORI

The correspondence should include any or all of the following keywords:

- UL1 TR000124
- Janina Jiang
- FR Doc. 2022-16867

The time frame for these records should be from August 1, 2022 to present.

If there are any fees for searching or copying these records, please inform me if the cost will exceed $25.00. However, I would also like to request a waiver of all fees in that the disclosure of the requested information is in the public interest and I am requesting this information as a representative of news media (Retraction Watch, a non-profit organization). My request is pertinent to the news gathering process, and this information is not being sought for commercial purposes.

If you have any questions as to the information requested or scope, please feel free to contact me at aabritis@gmail.com or abritis@retractionwatch.com, or by phone at 727-432-6499. If you expect a significant delay in responding to or in fulfilling this request, please contact me with information about when I might expect copies or the ability to inspect the requested records.

Thank you very kindly for any assistance in this matter.

Alison Abritis, Ph.D
RetractionWatch.com
The Center For Scientific Integrity
121 W 36th St.
Suite 209
New York, NY 10018
aabritis@gmail.com
abritis@retractionwatch.com
ph: (727) 432-6499

Hi Karen [redacted (b)(6); (b)(7)(C)]

I have placed all of the ORI 2022-12 case-related emails that I was sent or copied on, that contained the keywords listed by the requestor, from August 1st to the present, in the following S drive folder:
[redacted (b)(6); (b)(7)(C)]

Please let me know when you do receive the request from the FOIA office and start to redact the material. I'll add more relevant emails to the folder as I receive them.

From: (b)(6): HHS/OASH)
To: (b)(6); (b)(7)(C)
Cc: (b)(6): HHS/OASH); Runko, Alexander (HHS/OASH); Jones, Wanda K. (DHHS/OS/OASH); S(b)(6); (b)(7)(C); (HHS/OASH)
Subject: ORI 2022-12 (DIO 7163)
Date: Tuesday, July 26, 2022 6:48:55 PM
Attachments: ORI 2022-12 Letter to Respondent.pdf
SIGNED - TAB A - ORI 2022-12 VSA.pdf

RE: ORI 2022-12 (DIO 7163)

Dr. Jiang,

Please find attached July 26,2022 Final Notification Letter and accompanying Executed Voluntary Settlement Agreement(VSA) from Wanda K. Jones, Dr. P.H. Acting Director, Office of Research Integrity(ORI) regarding Administrative Actions implemented in ORI 2022-12.

(b)(6); (b)(7)(C)

Office of Research Integrity

1101 Wootton Parkway

Ste 750

Rockville Maryland 20852

COR69a

VSA LETTER TO RESPONDENT

WILL BE SENT SEPARATELY WITH A DIGITAL SIGNATURE

VOLUNTARY SETTLEMENT AGREEMENT

This Voluntary Settlement Agreement (Agreement) is entered into by and between the United States Department of Health and Human Services (HHS) and Janina Jiang, M.D., Ph.D., (Respondent) (collectively, "the Parties").

The purpose of this Agreement is to settle the HHS Office of Research Integrity's (ORI's) research misconduct proceeding against Respondent, who was an Assistant Researcher in the Department of Pathology & Laboratory Medicine at the David Geffen School of Medicine, University of California, Los Angeles (UCLA).

Based on the report of an investigation conducted by UCLA and additional analysis conducted by ORI in its oversight review, ORI finds that Respondent engaged in research misconduct in research included in grant applications submitted for U.S. Public Health Service (PHS) funds, specifically R43 CA228629-01 submitted to the National Cancer Institute (NCI), National Institutes of Health (NIH), UL TR000124 submitted to the National Center for Advancing Translational Sciences (NCATS), NIH, and P01 AI131294-01, R01 AI126914-01, R21 AI131013-01, R21 AI131451-01, R21 AI131451-01A1, R21 AI142068-01, R43 AI136224-01, R44 AI126960-01, and R44 AI128983-01 submitted to the National Institute of Allergy and Infectious Diseases, NIH.

ORI finds that Respondent engaged in research misconduct by knowingly and recklessly falsifying and/or fabricating flow cytometry data that were included in the following eleven (11) grant applications submitted for PHS funds:

- R43 CA228629-01, "CTL Based Therapeutic Vaccine to Prevent or Interrupt HPV Mediated Oncogenesis," submitted to NCI, NIH, Awarded Project Dates: September 18, 2018-February 29, 2020.

- UL1 TR000124, "UCLA Clinical and Translational Science Institute," submitted to NCATS, NIH, Awarded Project Dates: June 1, 2011-August 31, 2016.

- P01 AI131294-01, "Defining Factors Controlling HIV Rebound," submitted to NIAID, NIH, Awarded Project Dates: August 10, 2017-July 31, 2022.

- R01 AI126914-01, "A Recombinant Human Vault CTL-Based HIV Vaccine Component," submitted to NIAID, NIH, on December 23, 2015.

- R21 AI131013-01, "A Novel Cellular Immune Zika Vaccine," submitted to NIAID, NIH, on June 14, 2016.

- R21 AI131451-01, "A Novel Therapeutic Vaccine for HPV Oncogenesis," submitted to NIAID, NIH, on June 14, 2016.

- R21 AI131451-01A1, "A Novel Therapeutic Vaccine for HPV Oncogenesis," submitted to NIAID, NIH, on June 13, 2017.

- R21 AI142068-01, "A Novel Therapeutic Vaccine for HPV Oncogenesis," submitted to NIAID, NIH, on February 12, 2018.

- R43 AI136224-01, "Development of A Novel Pan-Serovar Vaccine for Chlamydia," submitted to NIAID, NIH, on April 5, 2017.

- R44 AI126960-01, "Novel Pan-Serovar Vaccine for Chlamydia," submitted to NIAID, NIH, on January 4, 2016.

- R44 AI128983-01, "Design of a Novel CTL Retargeting Therapeutic HIV Vaccine," submitted to NIAID, NIH, on April 2, 2016.

ORI finds that Respondent knowingly and recklessly falsified and/or fabricated flow cytometry data to represent interferon-γ (IFN-γ) expression in immune cells of mice administered with human recombinant vaults such that the represented data were incompatible with the raw experimental data. Specifically, Respondent falsified and/or fabricated flow cytometry data to represent:

- IFN-γ expression in the immune cells of mice injected subcutaneously or intranasally with human recombinant vaults containing HIV Gag peptides such that the vaccinated arm of the experiment showed antigen-specific T-cell responses in:

  - Figure 6 of UL1 TR000124
  - Figure 2 of R43 CA228629
  - Figure 8 of R21 AI131451-01
  - Figure 9 of R21 AI131451-01A1
  - Figure 9 of R44 AI126960-01
  - Figure 3 of R43 AI136224-01
  - Figure 9 of R21 AI131013
  - Figure 7 of R01 AI126914
  - Figure 7 of R44 AI128983
  - Figures 8A and 8B of R21 AI142068-01

- increased IFN-γ expression in the immune cells of mice injected with human recombinant vaults containing HPV peptides in Figure 3 of R43 CA228629

- dose-dependent increase in IFN-γ expression in the immune cells of mice injected with human recombinant vaults containing HIV Gag peptides in Figure 8 of P01 AI131294 and Figure 8C of R21 AI142068-01

- IFN-γ expression in the immune cells of mice administered intranasally with human recombinant vaults containing HPV peptides in Figure 10 of R21 AI131451-01A1 and Figure 10 of R21 AI142068-01

- IFN-γ expression in the immune cells of mice administered orally with human recombinant vaults containing HIV Gag peptides in Figure 11 of R21 AI131451-01A1 and Figure 9 of R21 AI142068-01

- IFN-γ expression in the immune cells of mice immunized subcutaneously with increasing doses of human recombinant vaults containing HIV Gag-1 spanning peptides in Figure 14 of R01 AI126914 and Figure 13 of R44 AI128983

The Parties wish to conclude this matter without further expenditure of time, finances, or other resources. The Parties therefore agree to the following terms:

1. Respondent will not contest or appeal the ORI findings of research misconduct as set forth above.

2. Respondent will not contest or appeal the jurisdiction of ORI in this matter.

3. Respondent will have her research supervised for a period of three (3) years beginning with the effective date of this Agreement (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.

4. The requirements for Respondent's supervision plan are as follows:

    i. A committee of 2 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 three (3) years from the effective date of this Agreement. The committee will review Respondent'sprimary data 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 Respondent's research. 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 Respondent's data presented in the proposed application, report, manuscript, or abstract are supported by the research record.

5. 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 in the application, report, manuscript, or abstract.

6. 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.

7. 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.

8. Paragraphs 1 through 7 are material provisions of this Agreement. A violation of any of these material provisions, as determined by ORI after providing Respondent with notice of the alleged violation and an opportunity to respond in writing, constitutes sufficient cause for HHS to exclude Respondent pursuant to 2 C.F.R. Parts 180 and 376 (collectively "the Debarment Regulations"). ORI's determination of Respondent's violation is unappealable. If ORI determines Respondent violated this Agreement, Respondent will: (1) voluntarily exclude herself from any contracting or subcontracting with any agency of the U.S. Government and from eligibility for or involvement in nonprocurement and procurement transactions referred to as "covered transactions" in the Debarment Regulations; and (2) voluntarily exclude herself from serving in any advisory or consultant capacity to the PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee. The period of such voluntary exclusion will begin when ORI notifies Respondent of its determination and will be equal to the duration of the violation plus one year. During the period of such voluntary exclusion, Respondent will not apply for, permit her name to be used on an application for, receive, or be supported by funds of the United States Government and its agencies made available through contracts, subcontracts, or covered transactions. HHS will enter the voluntary exclusion in the General Services Administration's System for Award Management (SAM), and ORI will publish a notice of the determination of a violation of this Agreement and Respondent's exclusion in the *Federal Register*.

9. ORI will close this research misconduct proceeding as of the effective date of this Agreement.

10. In accordance with its normal procedures, ORI will provide public notice of this Agreement in the *Federal Register* and on the ORI website, and Respondent's current institution may be notified if the institution is the recipient of PHS funds. Pursuant to 42 C.F.R. § 93.409, settlement agreements are publicly available.

11. This Agreement will become binding only when it is signed by both Parties and will become effective on the date it is signed by HHS.

12. This Agreement contains the complete description of the understanding between the Parties with respect to the subject matter of this Agreement and supersedes all other agreements between the Parties. Any modifications must be set forth in writing and signed by all Parties. Respondent represents that she enters into this Agreement voluntarily with knowledge of the events described.

(b)(6); (b)(7)(C)

7/18/2022
Date

Janina Jiang, M.D., Ph.D., Respondent

(b)(6); (b)(7)(C)

07/22/2022
Date

Principal Deputy Assistant Secretary for Health
Office of the Assistant Secretary for Health
U.S. Department of Health and Human Services

From: Janina Jiang
To: Runko, Alexander (HHS/OASH)
Cc: (b)(6); (b)(7)(C)
Subject: Re: ORI 2022-12 revised VSA
Date: Thursday, July 21, 2022 12:20:58 PM
Attachments: (b)(6); (b)(7)(C)

Hi Dr. Runko,

(b)(6); (b)(7)(C) will get you updates then !

Best,
Janina

Sent from my iPhone

On Jul 19, 2022, at 4:12 AM, Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C) hhs.gov> wrote:

Dear Janina,

Thank you for signing the VSA. It will become effective once the authorized HHS official signs it (b)(6); (b)(7)(C) Once it is finalized, we will send you a copy. As per the terms of the agreement, you will need a supervision plan in place for you to use PHS (NIH) funds for your research. The supervision plan will have to be implemented by your institution and submitted to ORI for our review and approval. Please let me know if you, your institution, or the RIO have any questions regarding the supervision plan. We will send that statement as we discussed to the RIO.

Once again, I would like to thank you for your cooperation to settle this matter.

Best,
Alex

From: Janina Jiang (b)(6); (b)(7)(C)
Sent: Tuesday, July 19, 2022 2:53 AM
To: Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C)
Cc (b)(6); (b)(7)(C) HHS/OASH (b)(6); (b)(7)(C)
Subject: Re: ORI 2022-12 revised VSA

Dear Runko,

Attached please find signed docs.

Best,
Janina

On Mon, Jul 18, 2022 at 1:29 PM Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C) wrote:

> It applies to the data present in the manuscript that was funded by PHS (NIH), or if the data appears in a proposal for PHS funding.
>
> **From:** Janina Jiang (b)(6); (b)(7)(C)
> **Sent:** Monday, July 18, 2022 4:21 PM
> **To:** Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C)
> **Cc:** (b)(6); (b)(7)(C)
> **Subject:** Re: ORI 2022-12 revised VSA
>
> Hi Dr. Runko,
>
> Just like to confirm that all these apply to PHS funded projects only, do I have this correct? Thanks!
>
> Best,
> Janina
>
> Sent from my iPhone
>
> > On Jul 18, 2022, at 12:17 PM, Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C) wrote:
> >
> > Janina,
> >
> > Below are the clarifying answers in response to your questions:
> >
> > 1. ORI can provide that statement to your institutional RIO when the VSA becomes finalized (once it is signed by you and the authorized HHS official).
> > 2. The supervisory committee must review your PHS-supported work in the manuscript before it is submitted to the journal, and provide a certification to ORI that your data was legitimately derived and represented. Your committee will work with you if there are any questions or ambiguity about your research. ORI will review the certification and if needed, ask for further

information.

3. The supervision period will become final after (b)(6); years from the effective date of the VSA. (b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

Let me know if you have any further questions.
-Alex

From: Janina Jiang (b)(6); (b)(7)(C)
Sent: Monday, July 18, 2022 2:44 PM
To: Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C)
Cc: (b)(6); (b)(7)(C)
Subject: Re: ORI 2022-12 revised VSA

Dear Dr. Runko,

Thank you so much for your cooperation on finalizing VSA. Here are a couple of points I would like to clarify before signing it:

1. Can you send the statement in your earlier corresponding email (shown below) to my institute counterpart who will execute this matter.

(b)(6); (b)(7)(C)

2. In (b)(6); how to execute it practically: (b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

Thanks, looking forward to your responses!

Best,
Janina

Sent from my iPhone

On Jul 15, 2022, at 1:39 PM, Runko, Alexander (HHS/OASH[(b)(6); (b)(7)(C)] wrote:

I have revised [(b)(6); (b)(7)(C)] to two members (attached). It is not possible to remove [(b)(6);] as it is part of the federal regulations and ORI policy. [(b)(6); (b)(7)(C)]
[(b)(6); (b)(7)(C)]
I have revised [(b)(6); (b)(7)(C)]
[(b)(6); (b)(7)(C)]

From: Janina Jiang <[(b)(6); (b)(7)(C)]
Sent: Friday, July 15, 2022 4:23 PM
To: Runko, Alexander (HHS/OASH)
[(b)(6); (b)(7)(C)]
Cc: [(b)(6); (b)(7)(C)]
Subject: Re: ORI 2022-12 revised VSA

Thanks Dr. Runko,

Also can we [(b)(6); (b)(7)(C)]
[(b)(6); (b)(7)(C)]
[(b)(6); (b)(7)(C)] Thanks.

Best,

Janina

Sent from my iPhone

> On Jul 15, 2022, at 12:17 PM, Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C) wrote:
>
> I have revised (b)(6); (b)(7)(C) and ii to incorporate your requested changes – please see the attached.
>
> **From:** Janina Jiang (b)(6); (b)(7)(C)
> **Sent:** Friday, July 15, 2022 3:07 PM
> **To:** Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C)
> **Cc:** (b)(6); (b)(7)(C) (HHS/OASH) (b)(6); (b)(7)(C)
> **Subject:** Re: ORI 2022-12 revised VSA
>
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>
> Best,
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> Janina
>
> Sent from my iPhone
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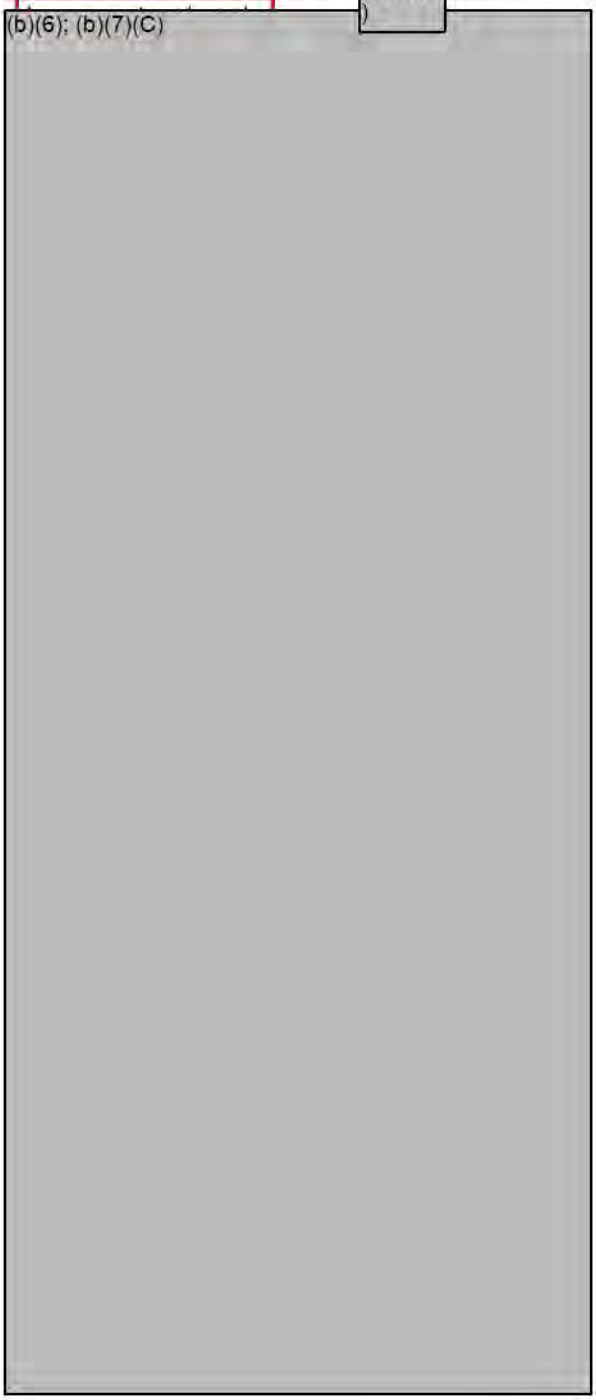
Hi Janina,

Thanks for your reply. To answer your questions, the requirements of the supervision plan gives some latitude to the institution conducting the supervision. (b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)



(b)(6); (b)(7)(C)

(b)(6); (b)(7)(C) I hope that this answers your questions.

-Alex

From: Janina Jiang (b)(6); (b)(7)(C)
Sent: Friday, July 15, 2022 2:16 PM
To: Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C)
Cc: (b)(6); (b)(7)(C) HHS/OASH) (b)(6); (b)(7)(C)
Subject: Re: ORI 2022-12 revised VSA

Hi Dr. Runko,

Here are some questions about VSA: (b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

(b)(6); (b)(7)(C) was not clear from our conversations! Please advise! Thanks!

Best,

Janina

Sent from my iPhone

On Jul 15, 2022, at 8:23 AM, Runko, Alexander (HHS/OASH) (b)(6): (b)(7)(C) wrote:

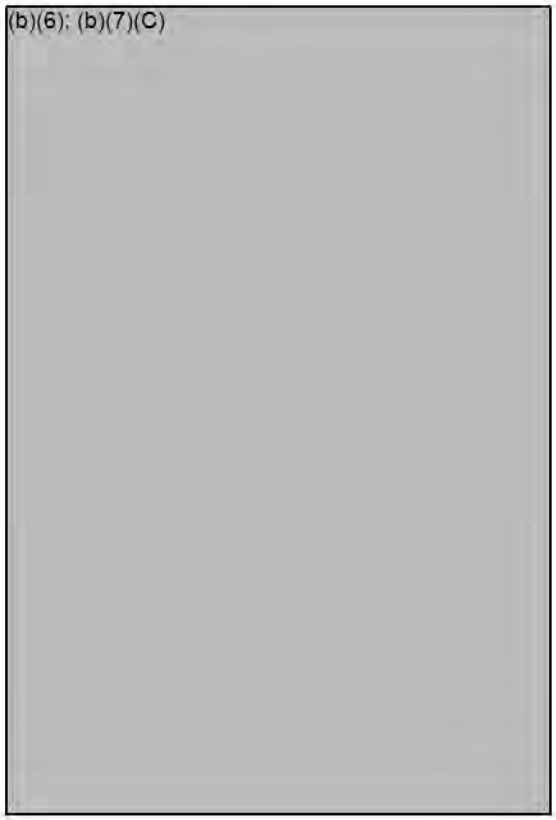
Dear Janina,

(b)(6): (b)(7)(C)

In order to reconcile this case with ORI, you can sign the VSA now so that you may continue to conduct research with PHS (NIH) funds without delay. (b)(6): (b)(7)(C)

(b)(6): (b)(7

(b)(6); (b)(7)(C)



ORI has an obligation to protect PHS research funds and the integrity of that funded research. ORI is required to adhere to the federal regulations at 42 C.F.R. Part 93, and we have our own policies, procedures, and timelines to abide by.

(b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

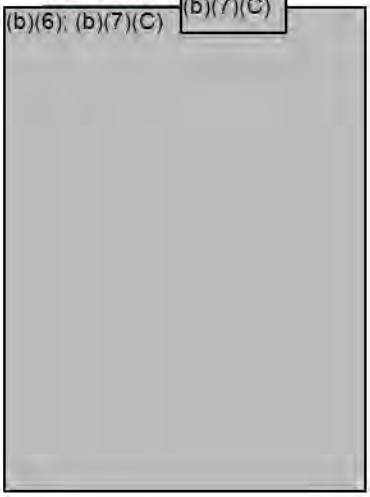
(b)(6); (b)(7)(C)

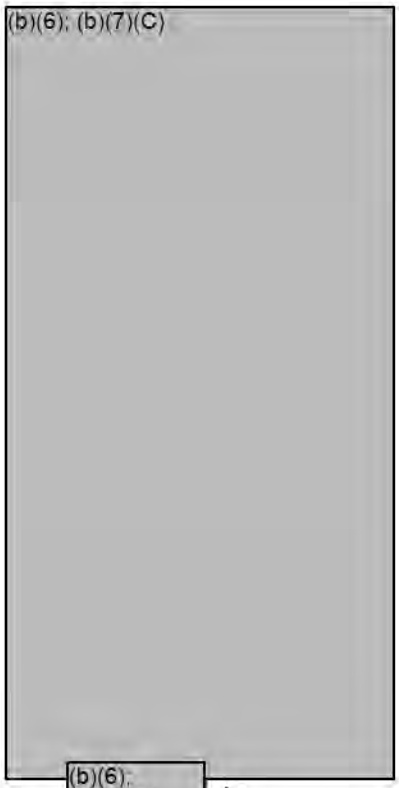
If ORI does not receive your

signature on the VSA by that date, we would have no other recourse than to contact the Research Integrity Officer (RIO) at your current institution at this time in order to preserve the integrity of PHS-funded research and to safeguard those PHS funds.

Under our regulatory authority at § 93.409(a), ORI may settle a research misconduct proceeding at any time that it concludes that the settlement is in the best interests of the Federal government and the public health or welfare. (b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)





(b)(6); (b)(7)(C) As prescribed in § 93.501, you would have the opportunity to contest ORI findings of research misconduct and HHS administrative actions by requesting an administrative hearing before an Administrative Law Judge (ALJ).

ORI anticipates that we can achieve an amicable resolution of this matter by receiving the VSA

with your signature by Monday (enclosed). If you need additional information, please contact me, (b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

Best,

Alex

Alexander Runko, Ph.D.

Director, Division of Investigative Oversight
Office of Research Integrity

Email: (b)(6); (b)(7)(C)

Office: (240) 453-8800

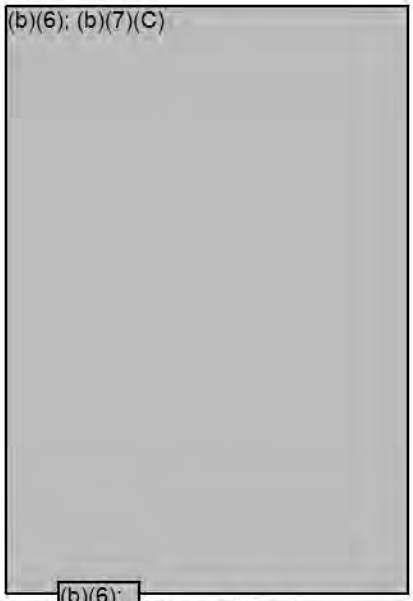
(b)(6); (b)(7)(C)

ori.hhs.gov/

OASH | Office of Research Integrity

From: Janina Jiang (b)(6); (b)(7)(C)
Sent: Friday, July 15, 2022 2:57 AM
To: Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C)
Cc: (b)(6); (b)(7)(C) (HHS/OASH) (b)(6); (b)(7)(C)
Subject: Re: ORI 2022-12 revised VSA

Dear Dr. Runko,



(b)(6); (b)(7)(Meanwhile, I greatly appreciate your understanding.

Thank you so much!

Best,

Janina

On Fri, Jul 8, 2022 at 7:23 AM Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C) wrote:

> Dear Dr. Jiang,
>
> Please let me know if you or your supervisor require any additional information or have questions regarding the terms of the voluntary settlement agreement (VSA) or the supervision plan. We look forward in your continuing cooperation to settle this matter with the revised VSA. Once you sign it, please return the VSA to ORI promptly so that it can be

signed by the authorized HHS Official, and then the VSA and supervision plan will become effective.

Best,

Alex

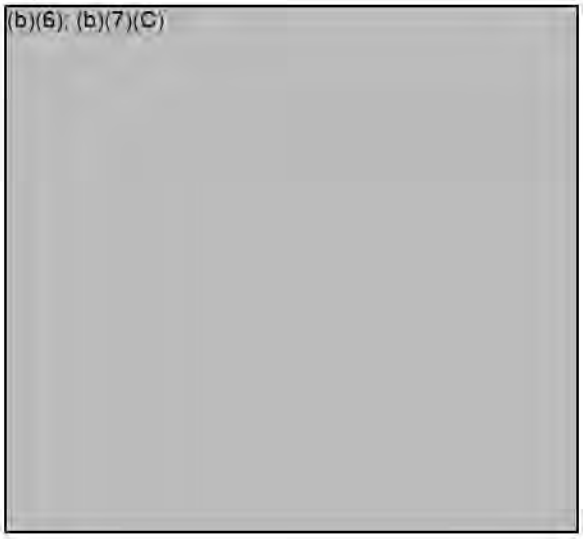
From: Runko, Alexander (HHS/OASH)
Sent: Thursday, June 30, 2022 6:10 PM
To: (b)(6); (b)(7)(C)
(b)(6); (b)(7)(C)
(HHS/OASH)
(b)(6); (b)(7)(C)
Subject: ORI 2022-12 revised VSA

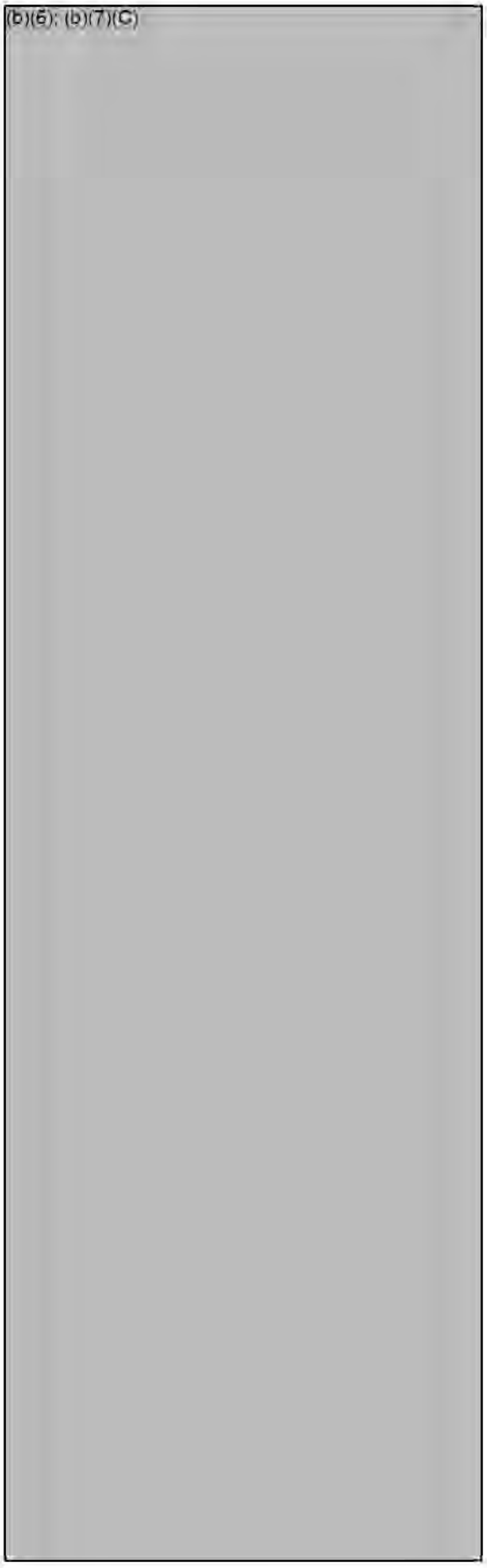
Dear Dr. Jiang,

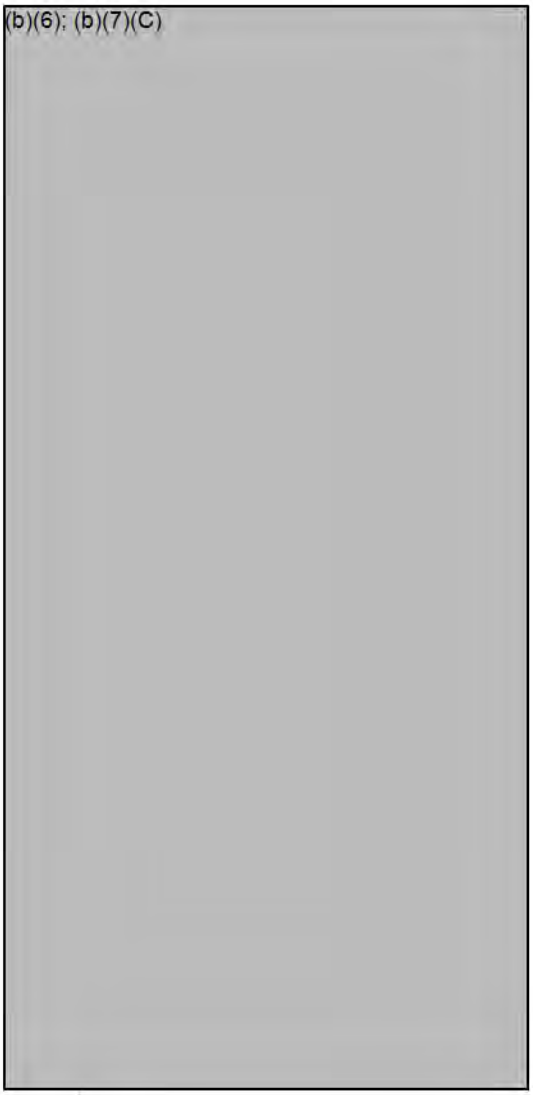
Thanks for speaking with us today, we heard your explanations

and concerns, and appreciate the time that you have taken in cooperating to come to an agreement to settle this matter. As discussed, enclosed is the voluntary supervision agreement (VSA) with the revisions, and below are the statements from ORI that you can share with your supervisor. Please do not hesitate to contact us with additional questions, or if your supervisor would like to schedule a call with us.

(b)(6); (b)(7)(C)




(b)(6); (b)(7)(C)



Best,

Alex

Alexander Runko, Ph.D.

Director,
Division of Investigative Oversight
Office of Research Integrity

Email:
(b)(6); (b)(7)(C)

Office: (240)
453-8800

(b)(6); (b)(7)(C)
(b)(6); (b)(7)(C)

ori.hhs.gov/

OASH | Office of Research Integrity

From: (b)(6); (b)(7)(C)
To: Jones, Wanda K. (DHHS/OS/OASH); Runko, Alexander (HHS/OASH); (b)(6); (b)(7)(C)
(b)(6); (b)(7)(C)
Cc: Wehner, Karen (HHS/OASH)
Subject: RE: ORI 2022-12 revised VSA
Date: Tuesday, July 19, 2022 8:03:12 AM
Attachments: image001.png
image002.png

Dear All,

Thank you! (b)(6); (b)(7)(C)
(b)(6); (b)(7)(C)

Regards,
(b)(6);

From: Jones, Wanda K. (DHHS/OS/OASH) <Wanda.Jones@hhs.gov>
Sent: Tuesday, July 19, 2022 7:56 AM
To: Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C)
(b)(6); (b)(7)(C)
Cc: Wehner, Karen (HHS/OASH) (b)(6); (b)(7)(C)
Subject: Re: ORI 2022-12 revised VSA

(b)(6); (b)(7)(C) Way to go (b)(6);

Get Outlook for iOS

From: Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C)
Sent: Tuesday, July 19, 2022 7:16:21 AM
(b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

Cc: Jones, Wanda K. (DHHS/OS/OASH) (b)(6); (b)(7)(C) ; Wehner, Karen (HHS/OASH) (b)(6); (b)(7)(C)

Subject: FW: ORI 2022-12 revised VSA

Congrats (b)(6); (b)(7)(C) VSA signed, (b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

From: Janina Jiang (b)(6); (b)(7)(C)
Sent: Tuesday, July 19, 2022 2:53 AM
To: Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C)
Cc: (b)(6); (b)(7)(C)
Subject: Re: ORI 2022-12 revised VSA

Dear Runko,

Attached please find signed docs.

Best,
Janina

On Mon, Jul 18, 2022 at 1:29 PM Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C) wrote:

> It applies to the data present in the manuscript that was funded by PHS (NIH), or if the data appears in a proposal for PHS funding.
>
> ---
>
> **From:** Janina Jiang (b)(6); (b)(7)(C)
> **Sent:** Monday, July 18, 2022 4:21 PM
> **To:** Runko, Alexander (HHS/OASH) <(b)(6); (b)(7)(C)
> **Cc:** (b)(6); (b)(7)(C)
> **Subject:** Re: ORI 2022-12 revised VSA
>
> Hi Dr. Runko,
>
> Just like to confirm that all these apply to PHS funded projects only, do I have this correct? Thanks!
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> Best,
> Janina

Sent from my iPhone

On Jul 18, 2022, at 12:17 PM, Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C)

Janina,

Below are the clarifying answers in response to your questions:

1. ORI can provide that statement to your institutional RIO when the VSA becomes finalized (once it is signed by you and the authorized HHS official).
2. The supervisory committee must review your PHS-supported work in the manuscript before it is submitted to the journal, and provide a certification to ORI that your data was legitimately derived and represented. Your committee will work with you if there are any questions or ambiguity about your research. ORI will review the certification and if needed, ask for further information.
3. The supervision period will become final after (b)(6); (b)(7)(years from the effective date of the VSA. (b)(6); (b)(7)(C) (b)(6); (b)(7)(C)

Let me know if you have any further questions.
-Alex

From: Janina Jiang (b)(6); (b)(7)(C)
Sent: Monday, July 18, 2022 2:44 PM
To: Runko, Alexander (HHS/OASH (b)(6); (b)(7)(C)
Cc: (b)(6); (b)(7)(C)
Subject: Re: ORI 2022-12 revised VSA

Dear Dr. Runko,

Thank you so much for your cooperation on finalizing VSA. Here are a couple of points I would like to clarify before signing it:

1. Can you send the statement in your earlier corresponding email (shown below) to my institute counterpart who will execute this matter.

(b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

2 (b)(6); (b)(7)(C) how to execute it practically: (b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

Thanks, looking forward to your responses!

Best,
Janina

Sent from my iPhone

On Jul 15, 2022, at 1:39 PM, Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C)

I have revised (b)(6); (b)(7)(C) to two members (attached). It is not possible to remove (b)(6); as it is part of the federal regulations and ORI policy. Since your institution will implement the supervision plan with the committee members, they will have to be informed of the VSA. I have revised (b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

From: Janina Jiang (b)(6); (b)(7)(C)
Sent: Friday, July 15, 2022 4:23 PM
To: Runko, Alexander (HHS/OASH (b)(6); (b)(7)(C)
Cc (b)(6); (b)(7)(C) C)
Subject: Re: ORI 2022-12 revised VSA

Thanks Dr. Runko,

Also can we (b)(6); (b)(7)(C)
(b)(6); (b)(7)(C)
Thanks.

Best,

Janina

Sent from my iPhone

On Jul 15, 2022, at 12:17 PM, Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C) wrote:

I have revised (b)(6); (b)(7)(C) incorporate your requested changes – please see the attached.

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(b)(6); (b)(7)(C)
Subject: Re: ORI 2022-12 revised VSA

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(b)(6); (b)(7)(C)
(b)(6); (b)(7)(C)
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Best,

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Sent from my iPhone

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Hi Janina,

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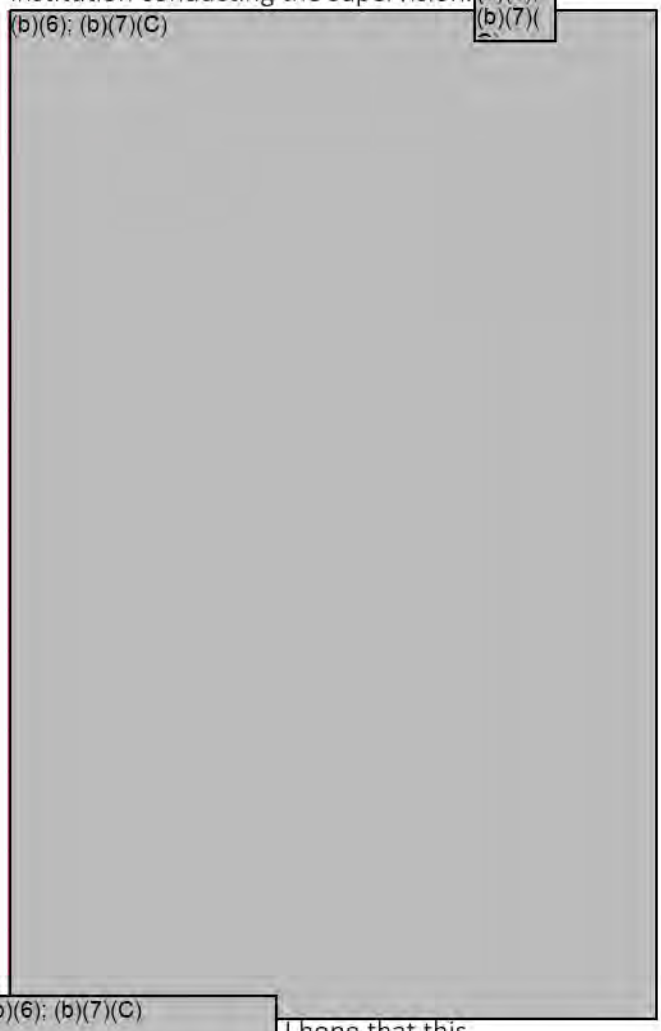

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-Alex

From: Janina Jian(b)(6); (b)(7)(C)
Sent: Friday, July 15, 2022 2:16 PM
To: Runko, Alexander (HHS/OASH)
(b)(6); (b)(7)(C)
Subject: Re: ORI 2022-12 revised VSA

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(b)(6); (b)(7)(C)
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Please advise! Thanks!

Best,

Janina

Sent from my iPhone

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> Runko, Alexander (HHS/OASH)
> (b)(6); (b)(7)(C)
> wrote:
>
> Dear Janina,
>
> (b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

In order to reconcile this case with ORI, you can sign the VSA now so that you may continue to conduct research with PHS (NIH) funds without delay. (b)(6);

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ORI has an obligation to protect PHS research funds and the integrity of that funded research. ORI is required to adhere to the federal regulations at 42 C.F.R. Part 93, and we have our own policies, procedures, and timelines to abide by. (b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

(b)(6); (b)(7)(C) If ORI does not receive your signature on the VSA by that date, we would have no other recourse than to contact the Research Integrity Officer (RIO) at your current

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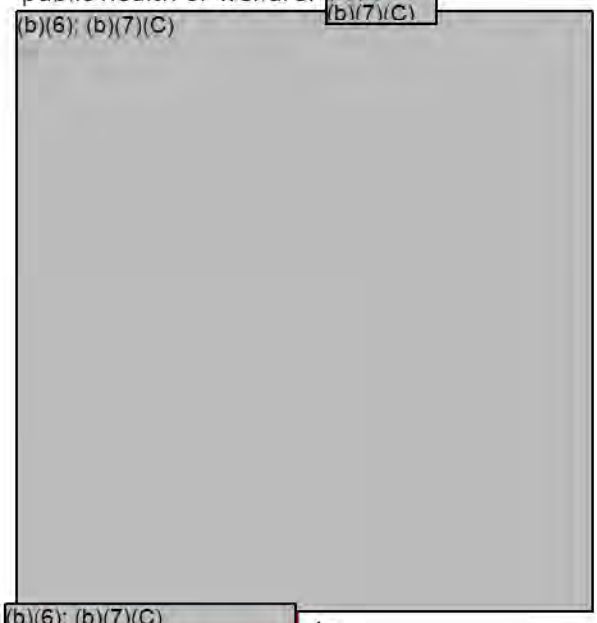

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ORI anticipates that we can achieve an amicable resolution of this matter by receiving the VSA with your signature by

Monday (enclosed). If you need additional information, please contact me. (b)(6); (b)(7)(C)

Best,

Alex

Alexander Runko, Ph.D.

Director, Division of Investigative Oversight
Office of Research Integrity

Email: (b)(6); (b)(7)(C)

Office: (240) 453-8800

(b)(6); (b)(7)(C)

ori.hhs.gov/

OASH | Office of Research Integrity

From: Janina Jiang (b)(6); (b)(7)(C)

Sent: Friday, July 15, 2022 2:57 AM

To: Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

Subject: Re: ORI 2022-12 revised VSA

Dear Dr. Runko,

(b)(6); (b)(7)(C)

Meanwhile, I greatly appreciate your understanding. Thank you so much!

Best,

Janina

On Fri, Jul 8, 2022 at 7:23 AM Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C) wrote:

> Dear Dr. Jiang,
>
> Please let me know if you or your supervisor require any additional information or have questions regarding the terms of the voluntary settlement agreement (VSA) or the supervision plan. We look forward in your continuing cooperation to

settle this matter with the revised VSA. Once you sign it, please return the VSA to ORI promptly so that it can be signed by the authorized HHS Official, and then the VSA and supervision plan will become effective.

Best,

Alex

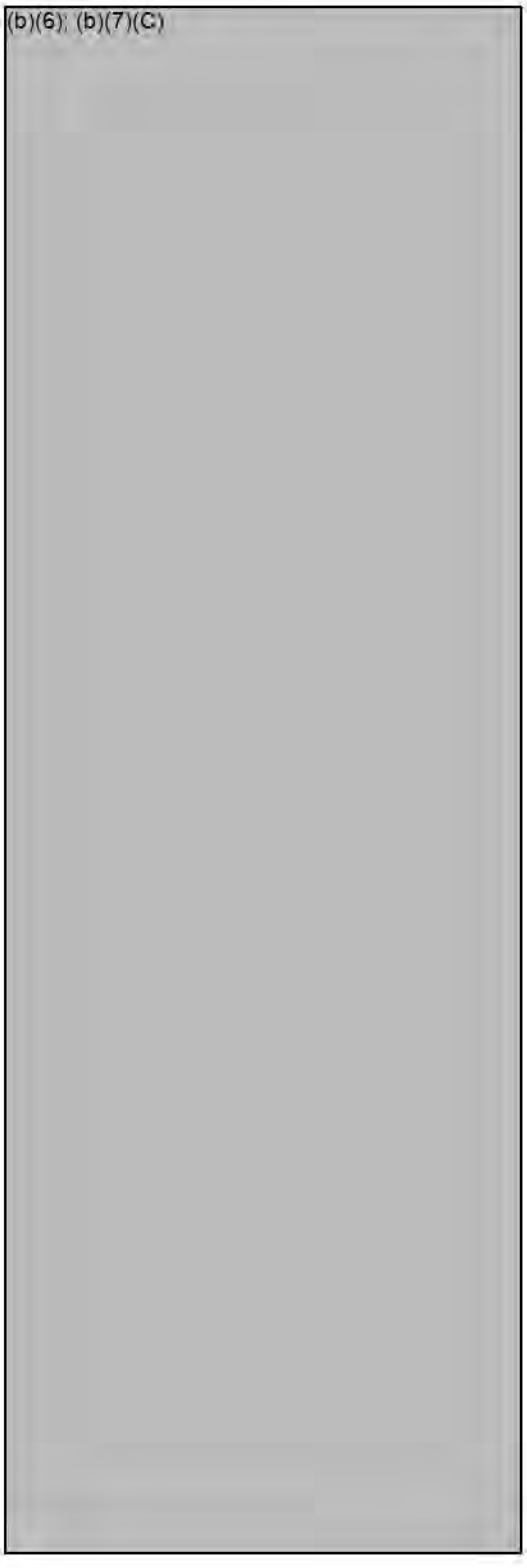
From: Runko, Alexander (HHS/OASH)
Sent: Thursday, June 30, 2022 6:10 PM
To (b)(6); (b)(7)(C)
Cc: Sharma, Anuj (HHS/OASH)
(b)(6); (b)(7)(C)
Subject: ORI 2022-12 revised VSA

Dear Dr. Jiang,

Thanks for speaking with us today, we heard your explanations and concerns, and appreciate the time that you have taken in cooperating to come to an agreement to settle this matter. As discussed, enclosed is the voluntary supervision agreement (VSA)

with the revisions, and below are the statements from ORI that you can share with your supervisor. Please do not hesitate to contact us with additional questions, or if your supervisor would like to schedule a call with us.

(b)(6); (b)(7)(C)



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From: Runko, Alexander (HHS/OASH)
To: Janina Jiang
Cc: (b)(6); (b)(7)(C)
Subject: RE: ORI 2022-12 revised VSA
Date: Tuesday, July 19, 2022 7:12:00 AM
Attachments: (b)(6); (b)(7)(C)

Dear Janina,

Thank you for signing the VSA. It will become effective once the authorized HHS official signs it, (b)(6); (b)(7)(C) Once it is finalized, we will send you a copy. As per the terms of the agreement, you will need a supervision plan in place for you to use PHS (NIH) funds for your research. The supervision plan will have to be implemented by your institution and submitted to ORI for our review and approval. Please let me know if you, your institution, or the RIO have any questions regarding the supervision plan. We will send that statement as we discussed to the RIO.

Once again, I would like to thank you for your cooperation to settle this matter.

Best,
Alex

From: Janina Jiang (b)(6); (b)(7)(C)
Sent: Tuesday, July 19, 2022 2:53 AM
To: Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C)
Cc: (b)(6); (b)(7)(C) (HHS/OASH) (b)(6); (b)(7)(C)
Subject: Re: ORI 2022-12 revised VSA

Dear Runko,

Attached please find signed docs.

Best,
Janina

On Mon, Jul 18, 2022 at 1:29 PM Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C) wrote:

> It applies to the data present in the manuscript that was funded by PHS (NIH), or if the data appears in a proposal for PHS funding.
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> **Cc:** (b)(6); (b)(7)(C)
> **Subject:** Re: ORI 2022-12 revised VSA

Hi Dr. Runko,

Just like to confirm that all these apply to PHS funded projects only, do I have this correct? Thanks!

Best,
Janina

Sent from my iPhone

On Jul 18, 2022, at 12:17 PM, Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C) wrote:

Janina,

Below are the clarifying answers in response to your questions:

1. ORI can provide that statement to your institutional RIO when the VSA becomes finalized (once it is signed by you and the authorized HHS official).
2. The supervisory committee must review your PHS-supported work in the manuscript before it is submitted to the journal, and provide a certification to ORI that your data was legitimately derived and represented. Your committee will work with you if there are any questions or ambiguity about your research. ORI will review the certification and if needed, ask for further information.
3. The supervision period will become final after (b)(6); years from the effective date of the VSA. (b)(6); (b)(7)(C)
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Let me know if you have any further questions.
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Thanks, looking forward to your responses!

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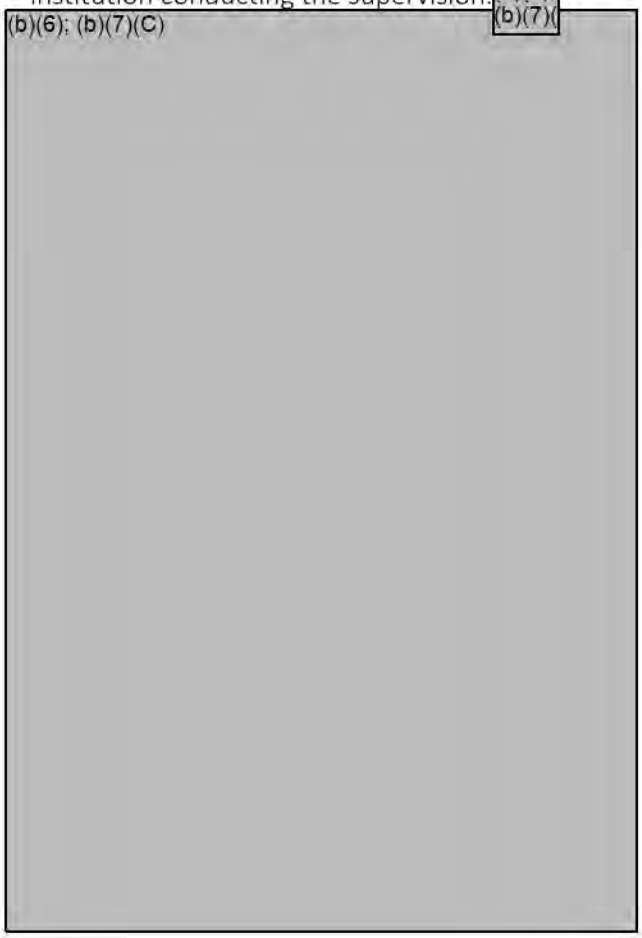

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-Alex

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Sent: Friday, July 15, 2022 2:16 PM
To: Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C)
Cc: (b)(6); (b)(7)(C) (b)(6); (b)(7)(C)
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Hi Dr. Runko,

Here are some questions about VSA:

(b)(6); (b)(7)(C)

I was not clear from our conversations!
Please advise! Thanks!

Best,

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wrote:

Dear Janina,

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In order to reconcile this case with ORI, you can sign the VSA now so that you may continue to conduct research with PHS (NIH) funds without delay.

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ORI has an obligation to protect PHS research funds and the integrity of that funded research. ORI is required to adhere to the federal regulations at 42 C.F.R. Part 93, and we have our own policies,

procedures, and timelines to abide by. (b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

(b)(6); If ORI does not receive your signature on the VSA by that date, we would have no other recourse than to contact the Research Integrity Officer (RIO) at your current institution at this time in order to preserve the integrity of PHS-funded research and to safeguard those PHS funds.

Under our regulatory authority at § 93.409(a), ORI may settle a research misconduct proceeding at any time that it concludes that the settlement is in the best interests of the Federal government and the public health or welfare. (b)(6); (b)(7)(C)

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(b)(6); (b)(7)(C) As prescribed in § 93.501, you would have the opportunity to contest ORI findings of research misconduct and HHS administrative actions by

requesting an administrative hearing before an Administrative Law Judge (ALJ).

ORI anticipates that we can achieve an amicable resolution of this matter by receiving the VSA with your signature by Monday (enclosed). If you need additional information, please contact me, (b)(6); (b)(7)(C)

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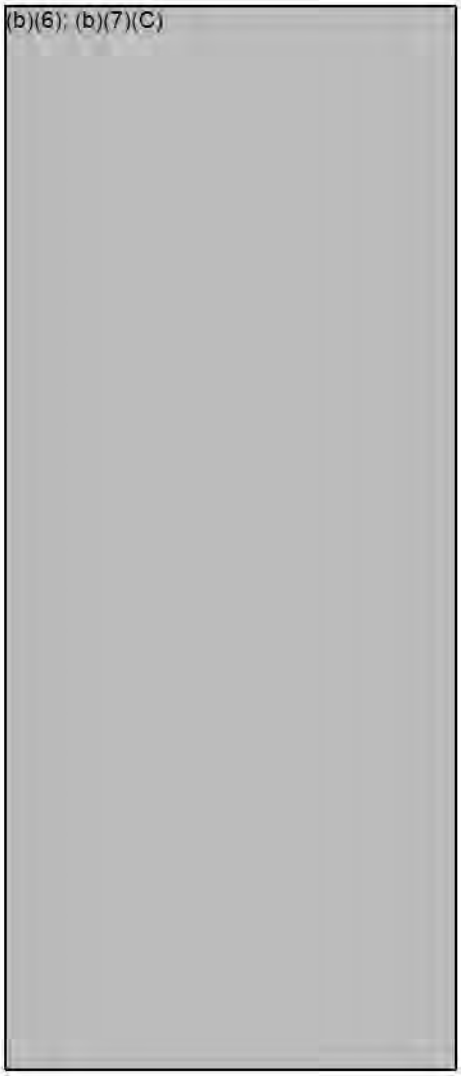

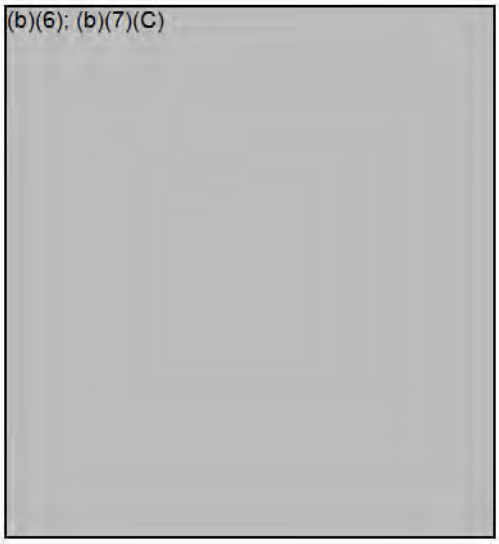

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From: Jones, Wanda K. (DHHS/OS/OASH)
To: (b)(6); (b)(7)(C)
Cc: Runko, Alexander (HHS/OASH)
Subject: FW: SCHEDULED: Document Number - 2022-16867
Date: Wednesday, August 3, 2022 9:37:53 AM

FYSA!

From: (b)(6); (b)(7)(C)
Sent: Wednesday, August 3, 2022 9:28 AM
To: (b)(6); (b)(7)(C) Jones, Wanda K. (DHHS/OS/OASH)
(b)(6); (b)(7)(C)
Subject: FW: SCHEDULED: Document Number - 2022-16867

Good morning,

Passing along the publication info below. Have a great day.

From: ExecSec.RegTeam (HHS) <(b)(6); (b)(7)(C)
Sent: Tuesday, August 2, 2022 3:35 PM
To: (b)(6); (b)(7)(C)
Cc: ExecSec.RegTeam (HHS) (b)(6); (b)(7)(C)
Subject: FW: SCHEDULED: Document Number - 2022-16867

H (b)(6);
Your document has been scheduled.
Thanks,
(b)(6);
(b)(7)(C)

From: noreply@fedreg.gov <noreply@fedreg.gov>
Sent: Tuesday, August 2, 2022 3:11 PM
To: ExecSec.RegTeam (HHS) <(b)(6); (b)(7)(C)
Cc: (b)(6); (b)(7)(C)
Subject: SCHEDULED: Document Number - 2022-16867

Please do not reply directly to this e-mail. If you have any questions or comments regarding this email, please contact (b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

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 Janina Jiang, M.D., Ph.D. (Respondent), former Assistant Researcher in the Department of Pathology & Laboratory Medicine at the David Geffen School of Medicine, University of California, Los Angeles (UCLA). Respondent engaged in research misconduct in research included in grant applications submitted for U.S. Public Health Service (PHS) funds, specifically R43 CA228629-01 submitted to the National Cancer Institute (NCI), National Institutes of Health (NIH), UL1 TR000124 submitted to the National Center for Advancing Translational Sciences (NCATS), NIH, and P01 AI131294-01, R01 AI126914-01, R21 AI131013-01, R21 AI131451-01, R21 AI131451-01A1, R21 AI142068-01, R43 AI136224-01, R44 AI126960-01, and R44 AI128983-01 submitted to the National Institute of Allergy and Infectious Diseases (NIAID), NIH. The administrative actions, including supervision for a period of three (3) years, were implemented beginning on July 22, 2022, and are detailed below.

From: Janina Jiang
To: Runko, Alexander (HHS/OASH)
Cc: (b)(6); (b)(7)(C)
Subject: Re: ORI 2022-12 revised VSA
Date: Monday, July 18, 2022 6:06:35 PM
Attachments: (b)(6); (b)(7)(C)

Thanks for the clarification. Will sign the revised VSA shortly!

Janina

Sent from my iPhone

> On Jul 18, 2022, at 1:29 PM, Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C)
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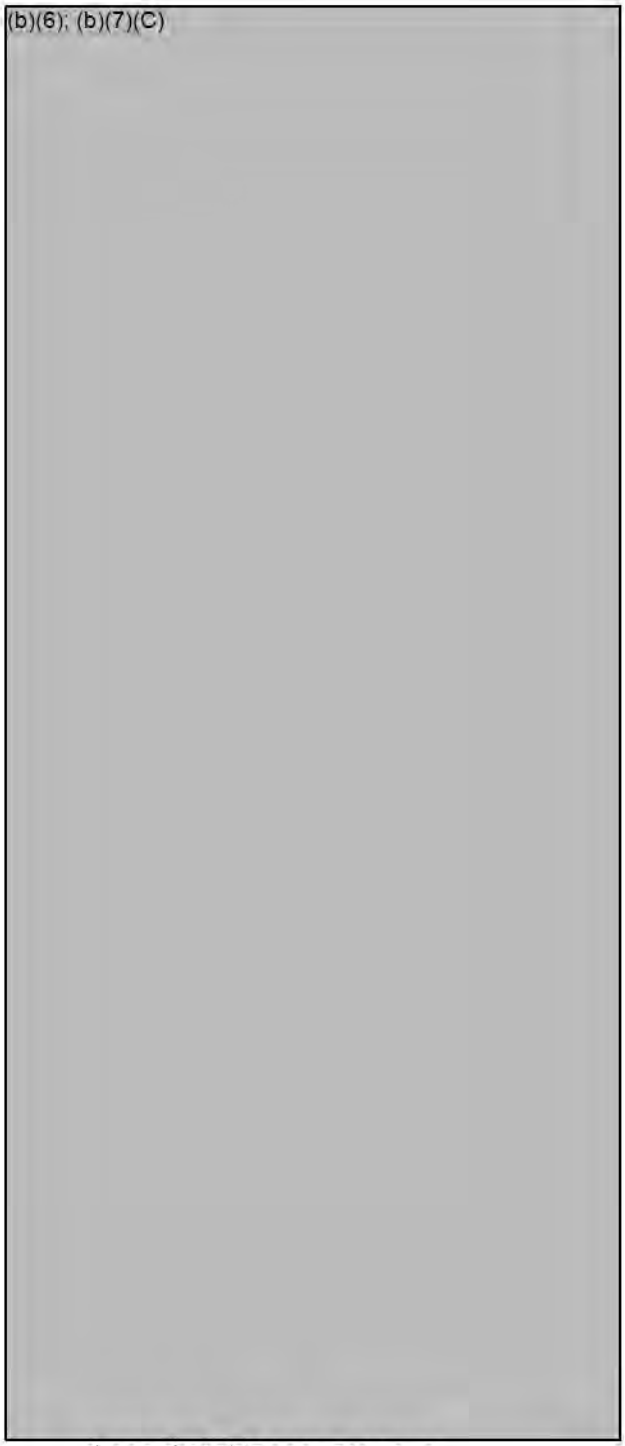

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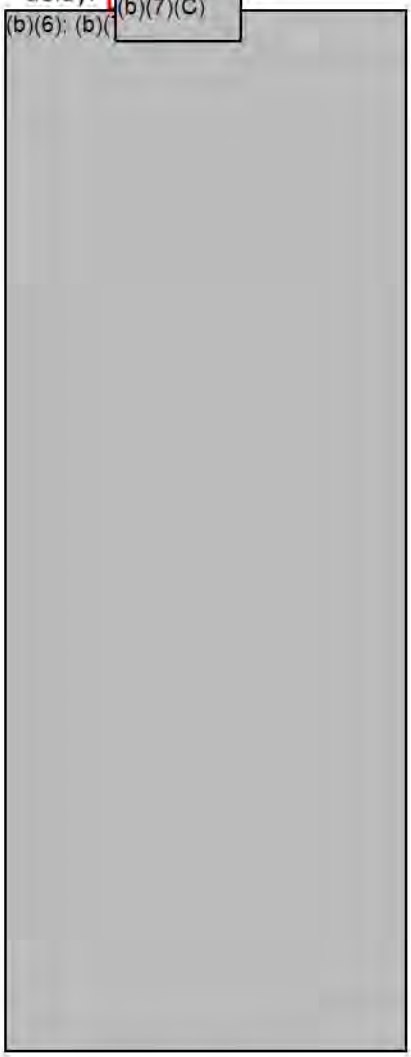

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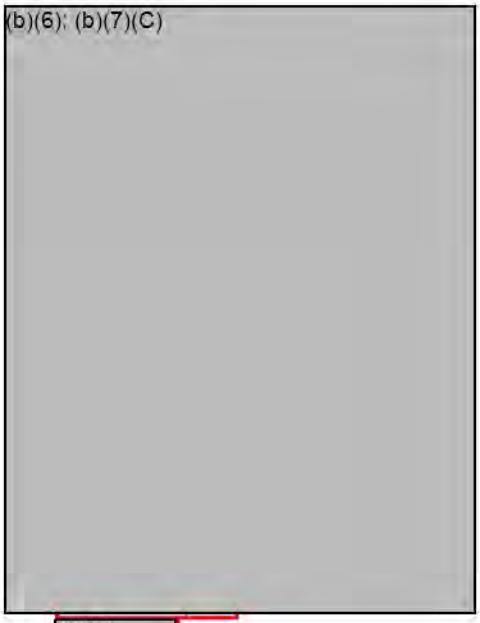

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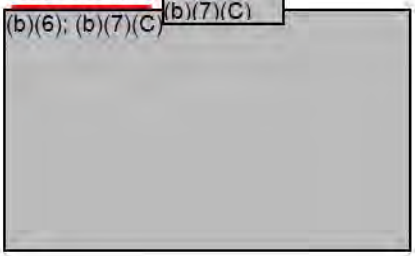

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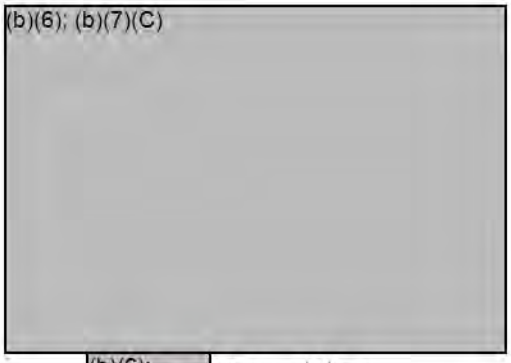
(b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)



(b)(6); Meanwhile, I greatly appreciate your understanding. Thank you so much!

Best,
Janina

On Fri, Jul 8, 2022 at 7:23 AM Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C) wrote:

> Dear Dr. Jiang,
>
> Please let me know if you or your supervisor require any additional information or have questions regarding the terms of the voluntary settlement agreement (VSA) or the supervision plan. We look forward in your continuing cooperation to settle this matter with the revised VSA. Once you sign it, please

return the VSA to ORI promptly so that it can be signed by the authorized HHS Official, and then the VSA and supervision plan will become effective.

Best,
Alex

From: Runko, Alexander (HHS/OASH)
Sent: Thursday, June 30, 2022 6:10 PM
To: (b)(6); (b)(7)(C)
(b)(6); (b)(7)(C)

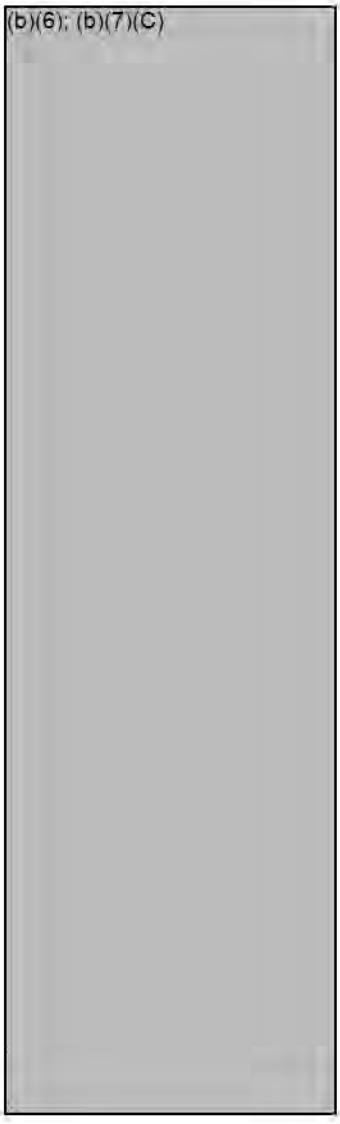
Subject: ORI 2022-12 revised VSA

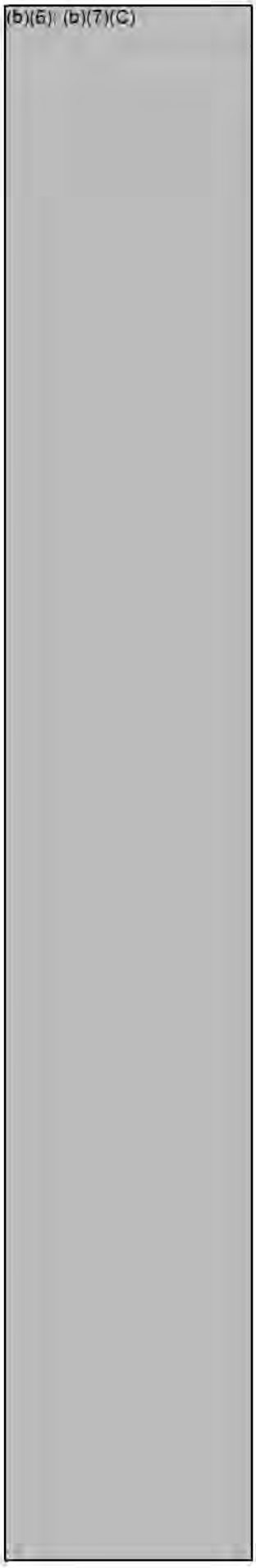
Dear Dr. Jiang,

Thanks for speaking with us today, we heard your explanations and concerns, and appreciate the time that you have taken in cooperating to come to an agreement to settle this matter.

As discussed, enclosed is the voluntary supervision agreement (VSA) with the revisions, and below are the statements from ORI that you can share with your supervisor. Please do not hesitate to contact us with additional questions, or if your supervisor would like to schedule a call with us.

(b)(6); (b)(7)(C)




(b)(6); (b)(7)(C)

Best,
Alex

Alexander Runko, Ph.D.
Director, Division of Investigative Oversight
Office of Research Integrity

Email: (b)(6); (b)(7)(C)
Office: (240) 453-8800
(b)(6); (b)(7)(C)
ori.hhs.gov

OASH | Office of Research Integrity

From: Runko, Alexander (HHS/OASH)
To: Janina Jiang
Cc: (b)(6); (b)(7)(C)
Subject: RE: ORI 2022-12 revised VSA
Date: Friday, July 15, 2022 2:39:00 PM
Attachments: (b)(6); (b)(7)(C)

Hi Janina,

Thanks for your reply. To answer your questions, the requirements of the supervision plan gives some latitude to the institution conducting the supervision. (b)(6); (b)(7)(C)
(b)(6); (b)(7)(C)
(b)(6); (b)(7)(C) I hope that this answers your questions.

-Alex

From: Janina Jiang (b)(6); (b)(7)(C)
Sent: Friday, July 15, 2022 2:16 PM
To: Runko, Alexander (HHS/OASH (b)(6); (b)(7)(C)
Cc: (b)(6); (b)(7)(C)
Subject: Re: ORI 2022-12 revised VSA

Hi Dr. Runko,

Here are some questions about VSA: (b)(6); (b)(7)(C)
(b)(6); (b)(7)(C) was not clear from our conversations! Please advise! Thanks!

Best,
Janina

Sent from my iPhone

On Jul 15, 2022, at 8:23 AM, Runko, Alexander (HHS/OASH)

(b)(6); (b)(7)(C) @hhs.gov> wrote:

Dear Janina,

(b)(6); (b)(7)(C)

In order to reconcile this case with ORI, you can sign the VSA now so that you may continue to conduct research with PHS (NIH) funds without delay. (b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

ORI has an obligation to protect PHS research funds and the integrity of that funded research. ORI is required to adhere to the federal regulations at 42 C.F.R. Part 93, and we have our own policies, procedures, and timelines to abide by. (b)(6); (b)(7)(C)

(b)(6); (b)(7)(C) . If ORI does not receive your signature on the VSA by that date, we would have no other recourse than to contact the Research Integrity Officer (RIO) at your current institution at this time in order to preserve the integrity of PHS-funded research and to safeguard those PHS funds.

Under our regulatory authority at § 93.409(a), ORI may settle a research misconduct proceeding at any time that it concludes that the settlement is in the best interests of the Federal government and the public health or welfare. (b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

(b)(6); (b)(7)(C) As prescribed in § 93.501, you would have the opportunity to contest ORI findings of research misconduct and HHS administrative actions by requesting an administrative hearing before an Administrative Law Judge (ALJ).

ORI anticipates that we can achieve an amicable resolution of this matter by receiving the VSA with your signature by Monday (enclosed). If you need additional information, please contact me, (b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

Best,
Alex

Alexander Runko, Ph.D.
Director, Division of Investigative Oversight
Office of Research Integrity

Email (b)(6); (b)(7)(C)
Office: (240) 453-8800
Desk: (b)(6); (b)(7)(C)
ori.hhs.gov/

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From: Janina Jiang (b)(6); (b)(7)(C)
Sent: Friday, July 15, 2022 2:57 AM
To: Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C)
Cc: (b)(6); (b)(7)(C)
Subject: Re: ORI 2022-12 revised VSA

Dear Dr. Runko,

(b)(6); (b)(7)(C)

(b)(6); (b)(7)(C) Meanwhile, I greatly appreciate your understanding. Thank you so much!

Best,
Janina

On Fri, Jul 8, 2022 at 7:23 AM Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C) > wrote:

> Dear Dr. Jiang,
>
> Please let me know if you or your supervisor require any additional information or have questions regarding the terms of the voluntary settlement agreement (VSA) or the supervision plan. We look forward in your continuing cooperation to settle this matter with the revised VSA. Once you sign it, please return the VSA to ORI promptly so that it can be signed by the authorized HHS Official, and then the VSA and supervision plan will become effective.
>
> Best,
> Alex

From: Runko, Alexander (HHS/OASH)
Sent: Thursday, June 30, 2022 6:10 PM
To: (b)(6); (b)(7)(C)
Cc: (b)(6); (b)(7)(C)
Subject: ORI 2022-12 revised VSA

Dear Dr. Jiang,

Thanks for speaking with us today, we heard your explanations and concerns, and appreciate the time that you have taken in cooperating to come to an agreement to settle this matter. As discussed, enclosed is the voluntary supervision agreement (VSA) with the revisions, and below are the statements from ORI that you can share with your supervisor. Please do not hesitate to contact us with additional questions, or if your supervisor would like to schedule a call with us.

(b)(6); (b)(7)(C)

Best,
Alex

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Email: (b)(6); (b)(7)(C)
Office: (240) 453-8800
Desk: (b)(6); (b)(7)(C)
ori.hhs.gov/

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From: Janina Jiang
To: Runko, Alexander (HHS/OASH)
Cc: (b)(6); (b)(7)(C)
Subject: Re: ORI 2022-12 revised VSA
Date: Friday, July 15, 2022 2:19:44 PM
Attachments: (b)(6); (b)(7)(C)
ORI 2022-12 (DIO 7163) VSA 07-15-2022.pdf

Hi Dr. Runko,

Here are some questions about VSA: (b)(6); (b)(7)(C)
(b)(6); (b)(7)(C)
(b)(6); (b)(7)(C) I was not clear from our conversations! Please advise! Thanks!

Best,
Janina

Sent from my iPhone

> On Jul 15, 2022, at 8:23 AM, Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C) wrote:
>
> Dear Janina,
>
> (b)(6); (b)(7)(C)
>
> In order to reconcile this case with ORI, you can sign the VSA now so that you may continue to conduct research with PHS (NIH) funds without delay. (b)(6); (b)(7)(C)
> (b)(6); (b)(7)(C)
>
> ORI has an obligation to protect PHS research funds and the integrity of that funded research. ORI is required to adhere to the federal regulations at 42 C.F.R. Part 93, and we have our own policies, procedures, and timelines to abide by. (b)(6); (b)(7)(C)
> (b)(6); (b)(7)(C) If ORI does not receive your signature on the VSA by that date, we would have no other recourse than to contact the Research Integrity Officer (RIO) at your current institution at this time in order to preserve the integrity of PHS-funded research and to safeguard those PHS

funds.

Under our regulatory authority at § 93.409(a), ORI may settle a research misconduct proceeding at any time that it concludes that the settlement is in the best interests of the Federal government and the public health or welfare. (b)(6); (b)(7)(C)
(b)(6); (b)(7)(C)
(b)(6); (b)(7)(C) As prescribed in § 93.501, you would have the opportunity to contest ORI findings of research misconduct and HHS administrative actions by requesting an administrative hearing before an Administrative Law Judge (ALJ).

ORI anticipates that we can achieve an amicable resolution of this matter by receiving the VSA with your signature by Monday (enclosed). If you need additional information, please contact me, (b)(6); (b)(7)(C)
(b)(6); (b)(7)(C)

Best,
Alex

Alexander Runko, Ph.D.
Director, Division of Investigative Oversight
Office of Research Integrity

Email: (b)(6); (b)(7)(C)
Office: (240) 453-8800
Desk: (b)(6); (b)(7)(C)
ori.hhs.gov/

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From: Janina Jiang (b)(6); (b)(7)(C)
Sent: Friday, July 15, 2022 2:57 AM
To: Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C)
Cc: S (b)(6); (b)(7)(C)
Subject: Re: ORI 2022-12 revised VSA

Dear Dr. Runko,

(b)(6); (b)(7)(C)

(b)(6); (b)(7)(C) Meanwhile, I greatly appreciate your understanding. Thank you so much!

Best,
Janina

On Fri, Jul 8, 2022 at 7:23 AM Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C) wrote:

> Dear Dr. Jiang,
>
> Please let me know if you or your supervisor require any additional information or have questions regarding the terms of the voluntary settlement agreement (VSA) or the supervision plan. We look forward in your continuing cooperation to settle this matter with the revised VSA. Once you sign it, please return the VSA to ORI promptly so that it can be signed by the authorized HHS Official, and then the VSA and supervision plan will become effective.
>
> Best,
> Alex
>
> ---
>
> **From:** Runko, Alexander (HHS/OASH)
> **Sent:** Thursday, June 30, 2022 6:10 PM
> **To** (b)(6); (b)(7)(C)
> **Cc:**
> **Subject:** ORI 2022-12 revised VSA
>
> Dear Dr. Jiang,
>
> Thanks for speaking with us today, we heard your explanations and concerns, and appreciate the time that you have taken in cooperating to come to an agreement to settle this matter. As discussed, enclosed is the voluntary supervision agreement (VSA) with the revisions, and below are the statements from ORI that you can share with your supervisor. Please do not hesitate to contact us with additional questions, or if your supervisor would like to schedule a call with us.
>
> (b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

Best,
Alex

Alexander Runko, Ph.D.
Director, Division of Investigative Oversight
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COR55a

DRAFT [VOLUNTARY SETTLEMENT AGREEMENT]

REDACTED IN FULL AS A PRE-DECISIONAL RECORD

Page 092 to Page 096

Withheld pursuant to exemption

(b)(5)

of the Freedom of Information Act

From: (b)(6); (b)(7)(C)
To: Runko, Alexander (HHS/OASH)
Subject: RE: ORI 2022-12 revised VSA
Date: Friday, July 15, 2022 10:54:37 AM
Attachments: (b)(6); (b)(7)(C)

Hi Alex,

This looks good. I just have a minor edit (in red below).

Thanks
Regards,
(b)(6);

From: Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C)
Sent: Friday, July 15, 2022 9:47 AM
To: (b)(6); (b)(7)(C)
Subject: RE: ORI 2022-12 revised VSA

Hi (b)(6); (b)(7)(C)

I plan to send her the following. Please review and let me know if anything else can be added. (b)(6); (b)(7)(C)
(b)(6); (b)(7)(C)

Thanks,
Alex

Dear Janina,

(b)(6); (b)(7)(C)

In order to reconcile this case with ORI, you can sign the VSA now so that you may continue to conduct research with PHS (NIH) funds without delay. (b)(6); (b)(7)(C)
(b)(6); (b)(7)(C)

ORI has an obligation to protect PHS research funds and the integrity of that funded research. ORI is required to adhere to the federal regulations at 42 C.F.R. Part 93, and we have our own policies, procedures, and timelines to abide by. (b)(6); (b)(7)(C)
(b)(6); (b)(7)(C) If ORI does not receive your signature on the VSA by that date, we

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(b)(6); (b)(7)(C)
(b)(6); . As prescribed in § 93.501, you would have the opportunity to contest ORI findings of research misconduct and HHS administrative actions by requesting an administrative hearing before an Administrative Law Judge (ALJ).

ORI anticipates that we can achieve an amicable resolution of this matter by receiving the VSA with your signature by Monday. If you need additional information, please contact me, (b)(6); (b)(7)(C)
(b)(6); (b)(7)(C)

Best,
Alex

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Office: (240) 453-8800
Desk: (b)(6); (b)(7)(C)
ori.hhs.gov/

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From: Janina Jiang (b)(6); (b)(7)(C)
Sent: Friday, July 15, 2022 2:57 AM
To: Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C)
Cc (b)(6); (b)(7)(C)
Subject: Re: ORI 2022-12 revised VSA

Dear Dr. Runko,

(b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)
(b)(6); (b)(7)(C) Meanwhile, I greatly appreciate your understanding. Thank you so much!

Best,
Janina

On Fri, Jul 8, 2022 at 7:23 AM Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C) wrote:

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>
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>
> Best,
> Alex
>
> **From:** Runko, Alexander (HHS/OASH)
> **Sent:** Thursday, June 30, 2022 6:10 PM
> **To:** (b)(6); (b)(7)(C)
> **Cc:**
> **Subject:** ORI 2022-12 revised VSA
>
> Dear Dr. Jiang,
>
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>
> (b)(6); (b)(7)(C)
>
> Best,

Alex

Alexander Runko, Ph.D.
Director, Division of Investigative Oversight
Office of Research Integrity

Email: (b)(6); (b)(7)(C)
Office: (240) 453-8800
Desk: (b)(6); (b)(7)(C)
ori.hhs.gov/

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From: Runko, Alexander (HHS/OASH)
To: (b)(6); (b)(7)(C)
Subject: FW: ORI 2022-12 revised VSA
Date: Friday, July 15, 2022 7:14:00 AM
Attachments: (b)(6); (b)(7)(C)

(b)(6); (b)(7)(C) I know that you are off today, so I will respond back to her stating that we acknowledge her situation, (b)(6); (b)(7)(C)
(b)(6); (b)(7)(C)
(b)(6); (b)(7)(C) In the meantime, I will have (b)(6); revise the current VSA (b)(6); (b)(7)(C)
(b)(6); (b)(7)(C)

From: Janina Jiang (b)(6); (b)(7)(C)
Sent: Friday, July 15, 2022 2:57 AM
To: Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C)
Cc: (b)(6); (b)(7)(C)
Subject: Re: ORI 2022-12 revised VSA

Dear Dr. Runko,

(b)(6); (b)(7)(C)
(b)(6); (b)(7)(C) Meanwhile, I greatly appreciate your understanding. Thank you so much!

Best,
Janina

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Sent: Thursday, June 30, 2022 6:10 PM
To: (b)(6); (b)(7)(C)
Cc:
Subject: ORI 2022-12 revised VSA

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(b)(6); (b)(7)(C)

Best,
Alex

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Director, Division of Investigative Oversight
Office of Research Integrity

Email: (b)(6); (b)(7)(C)
Office: (240) 453-8800
Desk: (b)(6); (b)(7)(C)
ori.hhs.gov/

OASH | Office of Research Integrity

From: Janina Jiang
To: Runko, Alexander (HHS/OASH)
Cc: (b)(6); (b)(7)(C)
Subject: Re: ORI 2022-12 revised VSA
Date: Monday, July 11, 2022 3:15:44 AM
Attachments: (b)(6); (b)(7)(C)

Dear Dr. Runko,

I acknowledge that I have received your previous email. I am still working on it, and will get back to you very soon.
Thank you!

Regards
Janina

On Fri, Jul 8, 2022 at 7:23 AM Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C) wrote:

> Dear Dr. Jiang,
>
> Please let me know if you or your supervisor require any additional information or have questions regarding the terms of the voluntary settlement agreement (VSA) or the supervision plan. We look forward in your continuing cooperation to settle this matter with the revised VSA. Once you sign it, please return the VSA to ORI promptly so that it can be signed by the authorized HHS Official, and then the VSA and supervision plan will become effective.
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> Alex
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> **From:** Runko, Alexander (HHS/OASH)
> **Sent:** Thursday, June 30, 2022 6:10 PM
> **To:** (b)(6); (b)(7)(C)
> **Cc:**
> **Subject:** ORI 2022-12 revised VSA

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(b)(6); (b)(7)(C)

Best,

Alex

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Director, Division of Investigative Oversight
Office of Research Integrity

Email: (b)(6); (b)(7)(C)

Office: (240) 453-8800

Desk (b)(6); (b)(7)(C)

ori.hhs.gov/

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adults in their transition from foster care to independent living in the areas of education, employment and earnings, housing and economic well-being, social support, well-being, health and safety, and criminal involvement. It focuses on helping young adults identify and achieve their goals while developing the skills necessary for independent living.

The evaluation is part of a larger project to help ACF build the evidence base in child welfare through rigorous evaluation of programs, practices, and policies. The activities and products from this project will contribute to evidence building in child welfare and help to determine the effectiveness of a program for youth formerly in foster care on young adult outcomes.

The implementation study will collect information through video conferences and site visits to the participating program and child welfare agency. Data collection activities for the implementation study began, as previously approved by OMB. Additional protocols are proposed as part of the implementation study. Proposed information collection activities include interviews and focus groups with administrators and staff from the program developer, child welfare agency, and program providers; online survey of program staff; interviews with youth who participated in the program; and focus groups with youth who participated in the program and who received services as usual.

Respondents: Program participants, young adults receiving services as usual, agency and program administrators and staff, other program stakeholders.

ANNUAL BURDEN ESTIMATES

Instrument	Respondents	Number of respondents (total over request period)	Number of responses per respondent (total over request period)	Average burden per response (in hours)	Total burden (in hours)	Annual burden (in hours)
Burden for previously approved, ongoing data collection						
Site Visit 2 Focus Group Guide for Staff.	LifeSet Specialists	12	1	1.5	18	9
LifeSet Team Supervisors						
Baseline Youth Survey	Youth Formerly in Foster Care.	470	1	0.6	282	141
Administrative data file	Agency and Program Staff	12	1	5	60	30
Burden for newly requested information collection						
Site Visit 3 Interview Guide for Administrators.	Child Welfare Agency Administrators. Licensed LifeSet Experts Provider Agency Administrators LifeSet Developer Administrators Provider Agency Administrators	22	1	1	22	11
Site Visit 3 Focus Group Guide for Staff.	LifeSet Specialists ..... LifeSet Team Supervisors Child Welfare Agency Caseworkers	28	1	1.5	42	21
LifeSet Specialist Survey	LifeSet Specialists	16	1	.3	5	3
Interview Guide for Youth ...	LifeSet Program Youth	12	1	1	12	6
Focus Group Guide for Youth.	LifeSet Program Youth ..... Services As Usual Youth	64	1	1.5	96	48

Estimated Total Annual Burden Hours: 269.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: 42 U.S.C. 677.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2022–16791 Filed 8–4–22; 8:45 am]

BILLING CODE 4184–25–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 Janina Jiang, M.D., Ph.D. (Respondent), former Assistant Researcher in the Department of Pathology & Laboratory Medicine at the David Geffen School of

Medicine, University of California, Los Angeles (UCLA). Respondent engaged in research misconduct in research included in grant applications submitted for U.S. Public Health Service (PHS) funds, specifically R43 CA228629–01 submitted to the National Cancer Institute (NCI), National Institutes of Health (NIH), UL1 TR000124 submitted to the National Center for Advancing Translational Sciences (NCATS), NIH, and P01 AI131294–01, R01 AI126914–01, R21 AI131013–01, R21 AI131451–01, R21 AI131451–01A1, R21 AI142068–01, R43 AI136224–01, R44 AI126960–01, and R44 AI128983–01 submitted to the National Institute of Allergy and Infectious Diseases (NIAID), NIH. The administrative actions, including supervision for a period of three (3) years, were implemented beginning on July 22, 2022, and are detailed below.

FOR FURTHER INFORMATION CONTACT: Wanda K. Jones, Dr.P.H., Acting 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:

Janina Jiang, M.D., Ph.D., University of California, Los Angeles: Based on the report of an investigation conducted by UCLA and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Janina Jiang, former Assistant Researcher in the Department of Pathology & Laboratory Medicine at the David Geffen School of Medicine, UCLA, engaged in research misconduct in research included in grant applications submitted for PHS funds, specifically R43 CA228629–01 submitted to NCI, NIH, UL1 TR000124 submitted to NCATS, NIH, and P01 AI131294–01, R01 AI126914–01, R21 AI131013–01, R21 AI131451–01, R21 AI131451–01A1, R21 AI142068–01, R43 AI136224–01, R44 AI126960–01, and R44 AI128983–01 submitted to NIAID, NIH.

ORI found that Respondent engaged in research misconduct by knowingly and recklessly falsifying and/or fabricating flow cytometry data that were included in the following eleven (11) grant applications submitted for PHS funds:

- R43 CA228629–01, ''CTL Based Therapeutic Vaccine to Prevent or Interrupt HPV Mediated Oncogenesis,'' submitted to NCI, NIH, Awarded Project Dates: September 18, 2018-February 29, 2020.
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- R21 AI131013–01, ''A Novel Cellular Immune Zika Vaccine,'' submitted to NIAID, NIH, on June 14, 2016.
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- R21 AI142068–01, ''A Novel Therapeutic Vaccine for HPV Oncogenesis,'' submitted to NIAID, NIH, on February 12, 2018.
- R43 AI136224–01, ''Development of A Novel Pan-Serovar Vaccine for Chlamydia,'' submitted to NIAID, NIH, on April 5, 2017.
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ORI found that Respondent knowingly and recklessly falsified and/or fabricated flow cytometry data to represent interferon-γ (IFN-γ) expression in immune cells of mice administered with human recombinant vaults such that the represented data were incompatible with the raw experimental data. Specifically, Respondent falsified and/or fabricated flow cytometry data to represent:

- IFN-γ expression in the immune cells of mice injected subcutaneously or intranasally with human recombinant vaults containing HIV Gag peptides such that the vaccinated arm of the experiment showed antigen-specific T-cell responses in:

—Figure 6 of UL1 TR000124
—Figure 2 of R43 CA228629–01
—Figure 8 of R21 AI131451–01
—Figure 9 of R21 AI131451–01A1
—Figure 9 of R44 AI126960–01
—Figure 3 of R43 AI136224–01
—Figure 9 of R21 AI131013–01
—Figure 7 of R01 AI126914–01
—Figure 7 of R44 AI128983–01
—Figures 8A and 8B of R21 AI142068–01

- increased IFN-γ expression in the immune cells of mice injected with human recombinant vaults containing HPV peptides in Figure 3 of R43 CA228629–01
- dose-dependent increase in IFN-γ expression in the immune cells of mice injected with human recombinant vaults containing HIV Gag peptides in Figure 8 of P01 AI131294–01 and Figure 8C of R21 AI142068–01
- IFN-γ expression in the immune cells of mice administered intranasally with human recombinant vaults containing HPV peptides in Figure 10 of R21 AI131451–01A1 and Figure 10 of R21 AI142068–01
- IFN-γ expression in the immune cells of mice administered orally with human recombinant vaults containing HIV Gag peptides in Figure 11 of R21 AI131451–01A1 and Figure 9 of R21 AI142068–01
- IFN-γ expression in the immune cells of mice immunized subcutaneously with increasing doses of human recombinant vaults containing HIV Gag-1 spanning peptides in Figure 14 of R01 AI126914–01 and Figure 13 of R44 AI128983–01

Dr. Jiang entered into a Voluntary Settlement Agreement (Agreement) and voluntarily agreed to the following:

(1) Respondent will have her research supervised for a period of three (3) years beginning on July 22, 2022 (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 two 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 three (3) years from the effective date of this Agreement. The committee will review Respondent's primary data 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 Respondent's research. 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 Respondent's 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 2, 2022.

Wanda K. Jones,

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

[FR Doc. 2022–16867 Filed 8–4–22; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2022–0258]

National Maritime Security Advisory Committee; Vacancies

AGENCY: U.S. Coast Guard, Department of Homeland Security.

ACTION: Request for applications.

SUMMARY: The U.S. Coast Guard seeks applications to fill two member vacancies on the National Maritime Security Advisory Committee (Committee). This Committee provides advice and makes recommendations to the Secretary of Homeland Security, via the Commandant of the U.S. Coast Guard, on matters relating to national maritime security, including on enhancing the sharing of information related to cybersecurity risks that may cause a transportation security incident, between relevant Federal agencies and State, local, and tribal governments; relevant public safety and emergency response agencies; relevant law enforcement and security organizations; maritime industry; port owners and operators; and terminal owners and operators.

DATES: Your completed application should reach the U.S. Coast Guard on or before September 6, 2022.

ADDRESSES: Applications should include a cover letter expressing interest in an appointment to the National Maritime Security Advisory Committee and a resume detailing the applicant's relevant experience for the position applied for, with a brief biography. Incomplete applications will not be considered. Applications should be submitted via email with the subject line ''Application for NMSAC'' to *ryan.f.owens@uscg.mil.*

FOR FURTHER INFORMATION CONTACT: Mr. Ryan Owens, Alternate Designated Federal Officer of the National Maritime Security Advisory Committee; telephone: 202–372–1108 or email at *ryan.f.owens@uscg.mil*

SUPPLEMENTARY INFORMATION: The National Maritime Security Advisory Committee is a Federal advisory committee. The Committee was established on December 4, 2018, by § 602 of the *Frank LoBiondo Coast Guard Authorization Act of 2018,* Public Law 115–282, 132 Stat. 4192, and is codified in 46 U.S.C. 70112. The Committee operates under the provisions of the *Federal Advisory Committee Act,* (5 U.S.C. Appendix), and 46 U.S.C. 15109. The National Maritime Security Advisory Committee provides advice, consults with, and makes recommendations to the Secretary of Homeland Security, via the Commandant of the Coast Guard, on matters relating to national maritime security, including on enhancing the sharing of information related to cybersecurity risks that may cause a transportation security incident, between relevant Federal agencies and—

A. State, local, and tribal governments;

B. relevant public safety and emergency response agencies;

C. relevant law enforcement and security organizations;

D. maritime industry;

E. port owners and operators; and

F. terminal owners and operators.

The Committee is required to meet at least once a year in accordance with 46 U.S.C. 15109(a). We expect the Committee will hold meetings at least twice a year, but it may meet more frequently.

All members serve at their own expense and receive no salary or other compensation from the Federal Government. Members may be reimbursed for travel and per diem in accordance with Federal Travel regulations.

Under the provisions in 46 U.S.C. 15109(f)(6), if you are appointed as a member of the Committee, your membership term will expire on December 31 of the third full year after the effective date of your appointment. In this solicitation for Committee members, we will consider applications for two (2) positions:

- Facilities owners and operators.
- State and local governments.

Each member of the Committee must have particular expertise, knowledge, and experience in matters relating to the function of the Committee, which is to advise the Secretary of Homeland Security on the matters described above.

Consistent with 46 U.S.C. 15109(f)(4), Committee members are required to apply for, obtain, and maintain a government national security clearance at the Secret level. The U.S. Coast Guard will sponsor and assist candidates with this process.

In order for the Department, to fully leverage broad-ranging experience and education, the National Maritime Security Advisory Committee must be diverse with regard to professional and technical expertise. The Department is committed to pursuing opportunities, consistent with applicable law, to compose a committee that reflects the diversity of the nation's people.

If you are interested in applying to become a member of the Committee, email your cover letter and resume along with the brief biography to *ryan.f.owens@uscg.mil* via the transmittal method in the **ADDRESSES** section by the deadline in the **DATES** section of this notice.

From: Janina Jiang
To: Runko, Alexander (HHS/OASH)
Cc: (b)(6); (b)(7)(C)
Subject: Re: ORI2022-12 (D107163)
Date: Monday, June 27, 2022 5:57:29 PM
Attachments: (b)(6);

Dear Dr. Runko,

Thur. Jun. 30. 4:30pm-5:30pm would work!
Thanks!

Janina

Sent from my iPhone

> On Jun 27, 2022, at 8:19 AM, Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C) wrote:
>
> Dear Dr. Jiang,
>
> I am acknowledging receipt of your messages. As of now, we are available during the following dates/times (all EST) this week for a phone call:
> Tuesday, June 28, 2pm-3pm, 4pm-5:30pm
> Thursday, June 30, 4:30pm-5:30pm
> Friday, July 1, 12pm-2pm
>
> Let us know of several time slots that you are available, and we will send you a MS Teams invite for a call.
>
> Best,
> Alex
>
> **Alexander Runko, Ph.D.**
> Director, Division of Investigative Oversight
> Office of Research Integrity
> <!--[if !vml]--> <!--[endif]-->
>
> **Email:** (b)(6); (b)(7)(C)
> **Office:** (240) 453-8800
> ori.hhs.gov/
>
> OASH | Office of Research Integrity

-----Original Message-----
From: (b)(6); (b)(7)(C)
Sent: Thursday, June 23, 2022 5:04 PM
To: (b)(6); (b)(7)(C)
Cc: Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C)
(HHS/OASH) (b)(6); (b)(7)(C)
Subject: RE: ORI2022-12 (D107163)

Dear Dr. Jiang,

Thank you for reaching out to ORI. Dr. Alexander Runko is out of office for the rest of this week. We will contact you back on Monday to schedule a phone call to discuss the case.

Best Regards,

(b)(6); (b)(7)(C)
Division of Investigative Oversight
Office of Research Integrity
1101 Wootton Parkway Suite 240
Rockville, MD 20852

Email: (b)(6); (b)(7)(C)
Desk: (b)(6); (b)(7)(C)

-----Original Message-----
From: Janina Jiang (b)(6); (b)(7)(C)
Sent: Thursday, June 23, 2022 2:54 PM
To: Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C)
Cc: (b)(6); (b)(7)(C)
Subject: ORI2022-12 (D107163)

Dear Dr. Alexander (b)(6);

I tried to reach you at your office, unfortunately was told you were out of office. I would like to set up an appointment with you to talk about this case in details over the phone. Please let me know your availabilities. Thank you so much! Great appreciate!

Best
Janina Jiang

Sent from my iPhone

From: (b)(6); (b)(7)(C)
To:
Cc: Runko, Alexander (HHS/OASH); (b)(6); (b)(7)(C) HS/OASH)
Subject: RE: ORI2022-12 (D107163)
Date: Thursday, June 23, 2022 5:04:17 PM

Dear Dr. Jiang,

Thank you for reaching out to ORI. Dr. Alexander Runko is out of office for the rest of this week. We will contact you back on Monday to schedule a phone call to discuss the case.

Best Regards,

(b)(6); (b)(7)(C)
Division of Investigative Oversight
Office of Research Integrity
1101 Wootton Parkway Suite 240
Rockville, MD 20852

Email: (b)(6); (b)(7)(C)
Desk:

-----Original Message-----
From: Janina Jiang (b)(6); (b)(7)(C)
Sent: Thursday, June 23, 2022 2:54 PM
To: Runko, Alexander (HHS/OASH (b)(6); (b)(7)(C)
Cc: (b)(6); (b)(7)(C) @hhs.gov>
Subject: ORI2022-12 (D107163)

Dear Dr. Alexander (b)(6); (b)(7)(C)

I tried to reach you at your office, unfortunately was told you were out of office. I would like to set up an appointment with you to talk about this case in details over the phone. Please let me know your availabilities. Thank you so much! Great appreciate!

Best
Janina Jiang

Sent from my iPhone

From: Janina Jiang
To: Runko, Alexander (HHS/OASH)
Cc: (b)(6); (b)(7)(C)
Subject: ORI2022-12 (D107163)
Date: Thursday, June 23, 2022 3:03:23 PM

Dear Dr. Alexander (b)(6); (b)(7)(C)

I tried to reach you at your office, unfortunately was told you were out of office. I would like to set up an appointment with you to talk about this case in details over the phone. Please let me know your availabilities. Thank you so much! Great appreciate!

Best
Janina Jiang

Sent from my iPhone

From: (b)(6); (b)(7)(C)
To: Runko, Alexander (HHS/OASH)
Subject: DIO 7163 revised
Date: Wednesday, June 8, 2022 12:55:54 PM
Attachments: DIO 7163 VSA_V3.docx
Directors memo_misconduct_V2.docx

Hi Alex,

Please find attached the revised memo and VSA. (b)(6); (b)(7)(C)
(b)(6); (b)(7)(C)

Thanks

Anuj

Page 114 to Page 141

Withheld pursuant to exemption

(b)(5)

of the Freedom of Information Act

From: (b)(6); (b)(7)(C)
To: Runko, Alexander (HHS/OASH)
Subject: RE: DIO7163
Date: Monday, June 6, 2022 3:04:35 PM
Attachments: DIO 7163 VSA_V2.docx
Directors memo_misconduct_V2.docx

Hi Alex,

Please find attached the revised VSA and the director's memo for DIO7163 for your review. As I mentioned before, I found the respondent (b)(6); (b)(7)(C)

Thanks,
(b)(6);

From: Runko, Alexander (HHS/OASH (b)(6); (b)(7)(C)
Sent: Tuesday, May 17, 2022 4:39 PM
To: (b)(6); (b)(7)(C)
Subject: RE: DIO7163

Hi (b)(6);

I made it as far as reviewing your VSA, please see the attached. I will be on annual leave on Friday and Monday (May 20 & 23), so I can discuss this with you next week. Hope your trip was enjoyable.

Best,
Alex

From: (b)(6); (b)(7)(C)
Sent: Friday, April 29, 2022 11:25 AM
To: Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C)
Subject: DIO7163

Hi Alex,

Please find the draft VSA and other documents related to 7163 here (b)(6); (b)(7)(C)
(b)(6); (b)(7)(C)

For the misconduct memo, please only see the Institutional investigation and DIO review sections, I have not worked on other sections yet.

I have asked (b)(6); to assign ORI accession number to the case.

Thanks,

Regards,

(b)(6);

Page 144 to Page 171

Withheld pursuant to exemption

(b)(5)

of the Freedom of Information Act

From: (b)(6); (b)(7)(C)
To: (b)(6); (b)(7)(C) (HHS/OASH); Runko, Alexander (HHS/OASH); (b)(6); (b)(7)(C)
(b)(6); (b)(7)(C)
Subject: Findings of Research Misconduct--Janina Jiang, M.D., Ph.D.
Date: Friday, August 5, 2022 11:02:58 AM
Attachments: (b)(6); (b)(7)(C)
FRN 2022-16867 Jiang.pdf

The notice of findings of research misconduct against Janina Jiang, M.D., Ph.D., was published on Friday, August 5, in the *Federal Register* at Vol. 87 No. 150 *Fed. Reg*. 48034-48035 (August 5, 2022).

The PDF file is attached.

Thanks,

(b)(6); (b)(7)(C)
Division of Investigative Oversight
Office of Research Integrity

Email: (b)(6); (b)(7)(C)
Desk: (

OASH Office of the Assistant Secretary for Health

adults in their transition from foster care to independent living in the areas of education, employment and earnings, housing and economic well-being, social support, well-being, health and safety, and criminal involvement. It focuses on helping young adults identify and achieve their goals while developing the skills necessary for independent living.

The evaluation is part of a larger project to help ACF build the evidence base in child welfare through rigorous evaluation of programs, practices, and policies. The activities and products from this project will contribute to evidence building in child welfare and help to determine the effectiveness of a program for youth formerly in foster care on young adult outcomes.

The implementation study will collect information through video conferences and site visits to the participating program and child welfare agency. Data collection activities for the implementation study began, as previously approved by OMB. Additional protocols are proposed as part of the implementation study. Proposed information collection activities include interviews and focus groups with administrators and staff from the program developer, child welfare agency, and program providers; online survey of program staff; interviews with youth who participated in the program; and focus groups with youth who participated in the program and who received services as usual.

Respondents: Program participants, young adults receiving services as usual, agency and program administrators and staff, other program stakeholders.

ANNUAL BURDEN ESTIMATES

Instrument	Respondents	Number of respondents (total over request period)	Number of responses per respondent (total over request period)	Average burden per response (in hours)	Total burden (in hours)	Annual burden (in hours)
Burden for previously approved, ongoing data collection						
Site Visit 2 Focus Group Guide for Staff.	LifeSet Specialists	12	1	1.5	18	9
LifeSet Team Supervisors						
Baseline Youth Survey	Youth Formerly in Foster Care.	470	1	0.6	282	141
Administrative data file	Agency and Program Staff	12	1	5	60	30
Burden for newly requested information collection						
Site Visit 3 Interview Guide for Administrators.	Child Welfare Agency Administrators. Licensed LifeSet Experts Provider Agency Administrators LifeSet Developer Administrators Provider Agency Administrators	22	1	1	22	11
Site Visit 3 Focus Group Guide for Staff.	LifeSet Specialists ..... LifeSet Team Supervisors Child Welfare Agency Caseworkers	28	1	1.5	42	21
LifeSet Specialist Survey	LifeSet Specialists	16	1	.3	5	3
Interview Guide for Youth ...	LifeSet Program Youth	12	1	1	12	6
Focus Group Guide for Youth.	LifeSet Program Youth ..... Services As Usual Youth	64	1	1.5	96	48

Estimated Total Annual Burden Hours: 269.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: 42 U.S.C. 677.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2022–16791 Filed 8–4–22; 8:45 am]

BILLING CODE 4184–25–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 Janina Jiang, M.D., Ph.D. (Respondent), former Assistant Researcher in the Department of Pathology & Laboratory Medicine at the David Geffen School of

Medicine, University of California, Los Angeles (UCLA). Respondent engaged in research misconduct in research included in grant applications submitted for U.S. Public Health Service (PHS) funds, specifically R43 CA228629–01 submitted to the National Cancer Institute (NCI), National Institutes of Health (NIH), UL1 TR000124 submitted to the National Center for Advancing Translational Sciences (NCATS), NIH, and P01 AI131294–01, R01 AI126914–01, R21 AI131013–01, R21 AI131451–01, R21 AI131451–01A1, R21 AI142068–01, R43 AI136224–01, R44 AI126960–01, and R44 AI128983–01 submitted to the National Institute of Allergy and Infectious Diseases (NIAID), NIH. The administrative actions, including supervision for a period of three (3) years, were implemented beginning on July 22, 2022, and are detailed below.

FOR FURTHER INFORMATION CONTACT: Wanda K. Jones, Dr.P.H., Acting 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:

Janina Jiang, M.D., Ph.D., University of California, Los Angeles: Based on the report of an investigation conducted by UCLA and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Janina Jiang, former Assistant Researcher in the Department of Pathology & Laboratory Medicine at the David Geffen School of Medicine, UCLA, engaged in research misconduct in research included in grant applications submitted for PHS funds, specifically R43 CA228629–01 submitted to NCI, NIH, UL1 TR000124 submitted to NCATS, NIH, and P01 AI131294–01, R01 AI126914–01, R21 AI131013–01, R21 AI131451–01, R21 AI131451–01A1, R21 AI142068–01, R43 AI136224–01, R44 AI126960–01, and R44 AI128983–01 submitted to NIAID, NIH.

ORI found that Respondent engaged in research misconduct by knowingly and recklessly falsifying and/or fabricating flow cytometry data that were included in the following eleven (11) grant applications submitted for PHS funds:

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- R21 AI131451–01, ''A Novel Therapeutic Vaccine for HPV Oncogenesis,'' submitted to NIAID, NIH, on June 14, 2016.
- R21 AI131451–01A1, ''A Novel Therapeutic Vaccine for HPV Oncogenesis,'' submitted to NIAID, NIH, on June 13, 2017.
- R21 AI142068–01, ''A Novel Therapeutic Vaccine for HPV Oncogenesis,'' submitted to NIAID, NIH, on February 12, 2018.
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ORI found that Respondent knowingly and recklessly falsified and/or fabricated flow cytometry data to represent interferon-γ (IFN-γ) expression in immune cells of mice administered with human recombinant vaults such that the represented data were incompatible with the raw experimental data. Specifically, Respondent falsified and/or fabricated flow cytometry data to represent:

- IFN-γ expression in the immune cells of mice injected subcutaneously or intranasally with human recombinant vaults containing HIV Gag peptides such that the vaccinated arm of the experiment showed antigen-specific T-cell responses in:

—Figure 6 of UL1 TR000124
—Figure 2 of R43 CA228629–01
—Figure 8 of R21 AI131451–01
—Figure 9 of R21 AI131451–01A1
—Figure 9 of R44 AI126960–01
—Figure 3 of R43 AI136224–01
—Figure 9 of R21 AI131013–01
—Figure 7 of R01 AI126914–01
—Figure 7 of R44 AI128983–01
—Figures 8A and 8B of R21 AI142068–01

- increased IFN-γ expression in the immune cells of mice injected with human recombinant vaults containing HPV peptides in Figure 3 of R43 CA228629–01
- dose-dependent increase in IFN-γ expression in the immune cells of mice injected with human recombinant vaults containing HIV Gag peptides in Figure 8 of P01 AI131294–01 and Figure 8C of R21 AI142068–01
- IFN-γ expression in the immune cells of mice administered intranasally with human recombinant vaults containing HPV peptides in Figure 10 of R21 AI131451–01A1 and Figure 10 of R21 AI142068–01
- IFN-γ expression in the immune cells of mice administered orally with human recombinant vaults containing HIV Gag peptides in Figure 11 of R21 AI131451–01A1 and Figure 9 of R21 AI142068–01
- IFN-γ expression in the immune cells of mice immunized subcutaneously with increasing doses of human recombinant vaults containing HIV Gag-1 spanning peptides in Figure 14 of R01 AI126914–01 and Figure 13 of R44 AI128983–01

Dr. Jiang entered into a Voluntary Settlement Agreement (Agreement) and voluntarily agreed to the following:

(1) Respondent will have her research supervised for a period of three (3) years beginning on July 22, 2022 (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 two 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 three (3) years from the effective date of this Agreement. The committee will review Respondent's primary data 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 Respondent's research. 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 Respondent's 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 2, 2022.

Wanda K. Jones,

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

[FR Doc. 2022–16867 Filed 8–4–22; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2022–0258]

National Maritime Security Advisory Committee; Vacancies

AGENCY: U.S. Coast Guard, Department of Homeland Security.

ACTION: Request for applications.

SUMMARY: The U.S. Coast Guard seeks applications to fill two member vacancies on the National Maritime Security Advisory Committee (Committee). This Committee provides advice and makes recommendations to the Secretary of Homeland Security, via the Commandant of the U.S. Coast Guard, on matters relating to national maritime security, including on enhancing the sharing of information related to cybersecurity risks that may cause a transportation security incident, between relevant Federal agencies and State, local, and tribal governments; relevant public safety and emergency response agencies; relevant law enforcement and security organizations; maritime industry; port owners and operators; and terminal owners and operators.

DATES: Your completed application should reach the U.S. Coast Guard on or before September 6, 2022.

ADDRESSES: Applications should include a cover letter expressing interest in an appointment to the National Maritime Security Advisory Committee and a resume detailing the applicant's relevant experience for the position applied for, with a brief biography. Incomplete applications will not be considered. Applications should be submitted via email with the subject line ''Application for NMSAC'' to *ryan.f.owens@uscg.mil.*

FOR FURTHER INFORMATION CONTACT: Mr. Ryan Owens, Alternate Designated Federal Officer of the National Maritime Security Advisory Committee; telephone: 202–372–1108 or email at *ryan.f.owens@uscg.mil*

SUPPLEMENTARY INFORMATION: The National Maritime Security Advisory Committee is a Federal advisory committee. The Committee was established on December 4, 2018, by § 602 of the *Frank LoBiondo Coast Guard Authorization Act of 2018,* Public Law 115–282, 132 Stat. 4192, and is codified in 46 U.S.C. 70112. The Committee operates under the provisions of the *Federal Advisory Committee Act,* (5 U.S.C. Appendix), and 46 U.S.C. 15109. The National Maritime Security Advisory Committee provides advice, consults with, and makes recommendations to the Secretary of Homeland Security, via the Commandant of the Coast Guard, on matters relating to national maritime security, including on enhancing the sharing of information related to cybersecurity risks that may cause a transportation security incident, between relevant Federal agencies and—

A. State, local, and tribal governments;

B. relevant public safety and emergency response agencies;

C. relevant law enforcement and security organizations;

D. maritime industry;

E. port owners and operators; and

F. terminal owners and operators.

The Committee is required to meet at least once a year in accordance with 46 U.S.C. 15109(a). We expect the Committee will hold meetings at least twice a year, but it may meet more frequently.

All members serve at their own expense and receive no salary or other compensation from the Federal Government. Members may be reimbursed for travel and per diem in accordance with Federal Travel regulations.

Under the provisions in 46 U.S.C. 15109(f)(6), if you are appointed as a member of the Committee, your membership term will expire on December 31 of the third full year after the effective date of your appointment. In this solicitation for Committee members, we will consider applications for two (2) positions:

- Facilities owners and operators.
- State and local governments.

Each member of the Committee must have particular expertise, knowledge, and experience in matters relating to the function of the Committee, which is to advise the Secretary of Homeland Security on the matters described above.

Consistent with 46 U.S.C. 15109(f)(4), Committee members are required to apply for, obtain, and maintain a government national security clearance at the Secret level. The U.S. Coast Guard will sponsor and assist candidates with this process.

In order for the Department, to fully leverage broad-ranging experience and education, the National Maritime Security Advisory Committee must be diverse with regard to professional and technical expertise. The Department is committed to pursuing opportunities, consistent with applicable law, to compose a committee that reflects the diversity of the nation's people.

If you are interested in applying to become a member of the Committee, email your cover letter and resume along with the brief biography to *ryan.f.owens@uscg.mil* via the transmittal method in the **ADDRESSES** section by the deadline in the **DATES** section of this notice.

adults in their transition from foster care to independent living in the areas of education, employment and earnings, housing and economic well-being, social support, well-being, health and safety, and criminal involvement. It focuses on helping young adults identify and achieve their goals while developing the skills necessary for independent living.

The evaluation is part of a larger project to help ACF build the evidence base in child welfare through rigorous evaluation of programs, practices, and policies. The activities and products from this project will contribute to evidence building in child welfare and help to determine the effectiveness of a program for youth formerly in foster care on young adult outcomes.

The implementation study will collect information through video conferences and site visits to the participating program and child welfare agency. Data collection activities for the implementation study began, as previously approved by OMB. Additional protocols are proposed as part of the implementation study. Proposed information collection activities include interviews and focus groups with administrators and staff from the program developer, child welfare agency, and program providers; online survey of program staff; interviews with youth who participated in the program; and focus groups with youth who participated in the program and who received services as usual.

Respondents: Program participants, young adults receiving services as usual, agency and program administrators and staff, other program stakeholders.

ANNUAL BURDEN ESTIMATES

Instrument	Respondents	Number of respondents (total over request period)	Number of responses per respondent (total over request period)	Average burden per response (in hours)	Total burden (in hours)	Annual burden (in hours)
Burden for previously approved, ongoing data collection						
Site Visit 2 Focus Group Guide for Staff.	LifeSet Specialists	12	1	1.5	18	9
LifeSet Team Supervisors						
Baseline Youth Survey	Youth Formerly in Foster Care.	470	1	0.6	282	141
Administrative data file	Agency and Program Staff	12	1	5	60	30
Burden for newly requested information collection						
Site Visit 3 Interview Guide for Administrators.	Child Welfare Agency Administrators. Licensed LifeSet Experts Provider Agency Administrators LifeSet Developer Administrators Provider Agency Administrators	22	1	1	22	11
Site Visit 3 Focus Group Guide for Staff.	LifeSet Specialists ..... LifeSet Team Supervisors Child Welfare Agency Caseworkers	28	1	1.5	42	21
LifeSet Specialist Survey	LifeSet Specialists	16	1	.3	5	3
Interview Guide for Youth ...	LifeSet Program Youth	12	1	1	12	6
Focus Group Guide for Youth.	LifeSet Program Youth ..... Services As Usual Youth	64	1	1.5	96	48

Estimated Total Annual Burden Hours: 269.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: 42 U.S.C. 677.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2022–16791 Filed 8–4–22; 8:45 am]

BILLING CODE 4184–25–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 Janina Jiang, M.D., Ph.D. (Respondent), former Assistant Researcher in the Department of Pathology & Laboratory Medicine at the David Geffen School of

Medicine, University of California, Los Angeles (UCLA). Respondent engaged in research misconduct in research included in grant applications submitted for U.S. Public Health Service (PHS) funds, specifically R43 CA228629–01 submitted to the National Cancer Institute (NCI), National Institutes of Health (NIH), UL1 TR000124 submitted to the National Center for Advancing Translational Sciences (NCATS), NIH, and P01 AI131294–01, R01 AI126914–01, R21 AI131013–01, R21 AI131451–01, R21 AI131451–01A1, R21 AI142068–01, R43 AI136224–01, R44 AI126960–01, and R44 AI128983–01 submitted to the National Institute of Allergy and Infectious Diseases (NIAID), NIH. The administrative actions, including supervision for a period of three (3) years, were implemented beginning on July 22, 2022, and are detailed below.

FOR FURTHER INFORMATION CONTACT: Wanda K. Jones, Dr.P.H., Acting 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:

Janina Jiang, M.D., Ph.D., University of California, Los Angeles: Based on the report of an investigation conducted by UCLA and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Janina Jiang, former Assistant Researcher in the Department of Pathology & Laboratory Medicine at the David Geffen School of Medicine, UCLA, engaged in research misconduct in research included in grant applications submitted for PHS funds, specifically R43 CA228629–01 submitted to NCI, NIH, UL1 TR000124 submitted to NCATS, NIH, and P01 AI131294–01, R01 AI126914–01, R21 AI131013–01, R21 AI131451–01, R21 AI131451–01A1, R21 AI142068–01, R43 AI136224–01, R44 AI126960–01, and R44 AI128983–01 submitted to NIAID, NIH.

ORI found that Respondent engaged in research misconduct by knowingly and recklessly falsifying and/or fabricating flow cytometry data that were included in the following eleven (11) grant applications submitted for PHS funds:

- R43 CA228629–01, ''CTL Based Therapeutic Vaccine to Prevent or Interrupt HPV Mediated Oncogenesis,'' submitted to NCI, NIH, Awarded Project Dates: September 18, 2018-February 29, 2020.
- UL1 TR000124, ''UCLA Clinical and Translational Science Institute,'' submitted to NCATS, NIH, Awarded Project Dates: June 1, 2011-August 31, 2016.
- P01 AI131294–01, ''Defining Factors Controlling HIV Rebound,'' submitted to NIAID, NIH, Awarded Project Dates: August 10, 2017-July 31, 2022.
- R01 AI126914–01, ''A Recombinant Human Vault CTL-Based HIV Vaccine Component,'' submitted to NIAID, NIH, on December 23, 2015.
- R21 AI131013–01, ''A Novel Cellular Immune Zika Vaccine,'' submitted to NIAID, NIH, on June 14, 2016.
- R21 AI131451–01, ''A Novel Therapeutic Vaccine for HPV Oncogenesis,'' submitted to NIAID, NIH, on June 14, 2016.
- R21 AI131451–01A1, ''A Novel Therapeutic Vaccine for HPV Oncogenesis,'' submitted to NIAID, NIH, on June 13, 2017.
- R21 AI142068–01, ''A Novel Therapeutic Vaccine for HPV Oncogenesis,'' submitted to NIAID, NIH, on February 12, 2018.
- R43 AI136224–01, ''Development of A Novel Pan-Serovar Vaccine for Chlamydia,'' submitted to NIAID, NIH, on April 5, 2017.
- R44 AI126960–01, ''Novel Pan-Serovar Vaccine for Chlamydia,'' submitted to NIAID, NIH, on January 4, 2016.
- R44 AI128983–01, ''Design of a Novel CTL Retargeting Therapeutic HIV Vaccine,'' submitted to NIAID, NIH, on April 2, 2016.

ORI found that Respondent knowingly and recklessly falsified and/or fabricated flow cytometry data to represent interferon-γ (IFN-γ) expression in immune cells of mice administered with human recombinant vaults such that the represented data were incompatible with the raw experimental data. Specifically, Respondent falsified and/or fabricated flow cytometry data to represent:

- IFN-γ expression in the immune cells of mice injected subcutaneously or intranasally with human recombinant vaults containing HIV Gag peptides such that the vaccinated arm of the experiment showed antigen-specific T-cell responses in:

—Figure 6 of UL1 TR000124
—Figure 2 of R43 CA228629–01
—Figure 8 of R21 AI131451–01
—Figure 9 of R21 AI131451–01A1
—Figure 9 of R44 AI126960–01
—Figure 3 of R43 AI136224–01
—Figure 9 of R21 AI131013–01
—Figure 7 of R01 AI126914–01
—Figure 7 of R44 AI128983–01
—Figures 8A and 8B of R21 AI142068–01

- increased IFN-γ expression in the immune cells of mice injected with human recombinant vaults containing HPV peptides in Figure 3 of R43 CA228629–01
- dose-dependent increase in IFN-γ expression in the immune cells of mice injected with human recombinant vaults containing HIV Gag peptides in Figure 8 of P01 AI131294–01 and Figure 8C of R21 AI142068–01
- IFN-γ expression in the immune cells of mice administered intranasally with human recombinant vaults containing HPV peptides in Figure 10 of R21 AI131451–01A1 and Figure 10 of R21 AI142068–01
- IFN-γ expression in the immune cells of mice administered orally with human recombinant vaults containing HIV Gag peptides in Figure 11 of R21 AI131451–01A1 and Figure 9 of R21 AI142068–01
- IFN-γ expression in the immune cells of mice immunized subcutaneously with increasing doses of human recombinant vaults containing HIV Gag-1 spanning peptides in Figure 14 of R01 AI126914–01 and Figure 13 of R44 AI128983–01

Dr. Jiang entered into a Voluntary Settlement Agreement (Agreement) and voluntarily agreed to the following:

(1) Respondent will have her research supervised for a period of three (3) years beginning on July 22, 2022 (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 two 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 three (3) years from the effective date of this Agreement. The committee will review Respondent's primary data 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 Respondent's research. 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 Respondent's 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 2, 2022.

Wanda K. Jones,

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

[FR Doc. 2022–16867 Filed 8–4–22; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2022–0258]

National Maritime Security Advisory Committee; Vacancies

AGENCY: U.S. Coast Guard, Department of Homeland Security.

ACTION: Request for applications.

SUMMARY: The U.S. Coast Guard seeks applications to fill two member vacancies on the National Maritime Security Advisory Committee (Committee). This Committee provides advice and makes recommendations to the Secretary of Homeland Security, via the Commandant of the U.S. Coast Guard, on matters relating to national maritime security, including on enhancing the sharing of information related to cybersecurity risks that may cause a transportation security incident, between relevant Federal agencies and State, local, and tribal governments; relevant public safety and emergency response agencies; relevant law enforcement and security organizations; maritime industry; port owners and operators; and terminal owners and operators.

DATES: Your completed application should reach the U.S. Coast Guard on or before September 6, 2022.

ADDRESSES: Applications should include a cover letter expressing interest in an appointment to the National Maritime Security Advisory Committee and a resume detailing the applicant's relevant experience for the position applied for, with a brief biography. Incomplete applications will not be considered. Applications should be submitted via email with the subject line ''Application for NMSAC'' to *ryan.f.owens@uscg.mil.*

FOR FURTHER INFORMATION CONTACT: Mr. Ryan Owens, Alternate Designated Federal Officer of the National Maritime Security Advisory Committee; telephone: 202–372–1108 or email at *ryan.f.owens@uscg.mil*

SUPPLEMENTARY INFORMATION: The National Maritime Security Advisory Committee is a Federal advisory committee. The Committee was established on December 4, 2018, by § 602 of the *Frank LoBiondo Coast Guard Authorization Act of 2018,* Public Law 115–282, 132 Stat. 4192, and is codified in 46 U.S.C. 70112. The Committee operates under the provisions of the *Federal Advisory Committee Act,* (5 U.S.C. Appendix), and 46 U.S.C. 15109. The National Maritime Security Advisory Committee provides advice, consults with, and makes recommendations to the Secretary of Homeland Security, via the Commandant of the Coast Guard, on matters relating to national maritime security, including on enhancing the sharing of information related to cybersecurity risks that may cause a transportation security incident, between relevant Federal agencies and—

A. State, local, and tribal governments;

B. relevant public safety and emergency response agencies;

C. relevant law enforcement and security organizations;

D. maritime industry;

E. port owners and operators; and

F. terminal owners and operators.

The Committee is required to meet at least once a year in accordance with 46 U.S.C. 15109(a). We expect the Committee will hold meetings at least twice a year, but it may meet more frequently.

All members serve at their own expense and receive no salary or other compensation from the Federal Government. Members may be reimbursed for travel and per diem in accordance with Federal Travel regulations.

Under the provisions in 46 U.S.C. 15109(f)(6), if you are appointed as a member of the Committee, your membership term will expire on December 31 of the third full year after the effective date of your appointment. In this solicitation for Committee members, we will consider applications for two (2) positions:

- Facilities owners and operators.
- State and local governments.

Each member of the Committee must have particular expertise, knowledge, and experience in matters relating to the function of the Committee, which is to advise the Secretary of Homeland Security on the matters described above.

Consistent with 46 U.S.C. 15109(f)(4), Committee members are required to apply for, obtain, and maintain a government national security clearance at the Secret level. The U.S. Coast Guard will sponsor and assist candidates with this process.

In order for the Department, to fully leverage broad-ranging experience and education, the National Maritime Security Advisory Committee must be diverse with regard to professional and technical expertise. The Department is committed to pursuing opportunities, consistent with applicable law, to compose a committee that reflects the diversity of the nation's people.

If you are interested in applying to become a member of the Committee, email your cover letter and resume along with the brief biography to *ryan.f.owens@uscg.mil* via the transmittal method in the **ADDRESSES** section by the deadline in the **DATES** section of this notice.

From: (b)(6); (b)(7)(C)
To: Runko, Alexander (HHS/OASH)
Subject: FW: DIO 7163
Date: Thursday, August 5, 2021 12:52:52 PM
Attachments: DIO 7163.pdf

Hi Alex,

I want to briefly discuss this case with you. (b)(6); (b)(7)(C)
(b)(6); (b)(7)(C)
(b)(6); (b)(7)(C)
I am available anytime this afternoon or tomorrow.

Thanks,
(b)(6);

From: (b)(6); (b)(7)(C)@research.ucla.edu> **On Behalf Of** Pollack, Ann
Sent: Thursday, August 5, 2021 12:23 PM
To: (b)(6); (b)(7)(C)
Cc: Pollack, Ann <(b)(6);@research.ucla.edu>
Subject: DIO 7163

Dear (b)(6); (b)(7)(C)

Please see the attached letter.

Thank you.

Ann Pollack
Associate Vice Chancellor – Research
Campus Research Compliance Coordinator
https://rpc.research.ucla.edu
10889 Wilshire Boulevard
Los Angeles, California 90095

Please note that I will be working remotely and calls are being forwarded.

UCLA Research & Creative Activities

Roger M. Wakimoto, Ph.D.
2248 Murphy Hall
Mail Code: (b)(6); (b)(7)(C)
Phone: (31(b)(7)(C)
Email: (b)(6); (b)(7)(C)

August 5, 2021

CONFIDENTIAL
VIA EMAIL

(b)(6); (b)(7)(C)
Division of Investigative Oversight
Office of Research Integrity
(b)(6); (b)(7)(C)

RE: DIO 7163

Dear (b)(6); (b)(7)(C)

I am writing to follow up on my letter of July 29, 2021 regarding the investigation into allegations of research misconduct against Janina Jiang, M.D., Ph.D., who conducted the research in question while working as an Assistant Researcher in the Department of Pathology & Laboratory Medicine in the David Geffen School of Medicine (DGSOM) at UCLA. (b)(6); (b)(7)(C)
(b)(6); (b)(7)(C)
(b)(6); (b)(7)(C) As the campus Research Integrity Officer, I will notify the Campus Human Resources Office of the outcome of the research misconduct investigation.

If you have any questions, please contact Ann Pollack, Associate Vice Chancellor-Research, at (b)(6); (b)(7)(C) or by e-mail at (b)(6); (b)(7)(C)

Sincerely,

(b)(6); (b)(7)(C)

Roger M. Wakimoto
Vice Chancellor for Research and Creative Activities
Research Integrity Officer

cc: Associate Vice Chancellor Ann Pollack

From: (b)(6); (b)(7)(C)
To:
Cc: (b)(6): HHS/OASH); Runko, Alexander (HHS/OASH); Jones, Wanda K. (DHHS/OS/OASH); (b)(6); (b)(6): /OASH)
Subject: ORI 2022-12 (DIO 7163)
Date: Tuesday, July 26, 2022 6:48:55 PM
Attachments: ORI 2022-12 Letter to Respondent.pdf
SIGNED - TAB A - ORI 2022-12 VSA.pdf

RE: ORI 2022-12 (DIO 7163)

Dr. Jiang,

Please find attached July 26,2022 Final Notification Letter and accompanying Executed Voluntary Settlement Agreement(VSA) from Wanda K. Jones, Dr. P.H. Acting Director, Office of Research Integrity(ORI) regarding Administrative Actions implemented in ORI 2022-12.

(b)(6); (b)(7)(C)

Office of Research Integrity

1101 Wootton Parkway

Ste 750

Rockville Maryland 20852

COR38a

VSA LETTER TO RESPONDENT

WILL BE SENT SEPARATELY WITH A DIGITAL SIGNATURE

VOLUNTARY SETTLEMENT AGREEMENT

This Voluntary Settlement Agreement (Agreement) is entered into by and between the United States Department of Health and Human Services (HHS) and Janina Jiang, M.D., Ph.D., (Respondent) (collectively, "the Parties").

The purpose of this Agreement is to settle the HHS Office of Research Integrity's (ORI's) research misconduct proceeding against Respondent, who was an Assistant Researcher in the Department of Pathology & Laboratory Medicine at the David Geffen School of Medicine, University of California, Los Angeles (UCLA).

Based on the report of an investigation conducted by UCLA and additional analysis conducted by ORI in its oversight review, ORI finds that Respondent engaged in research misconduct in research included in grant applications submitted for U.S. Public Health Service (PHS) funds, specifically R43 CA228629-01 submitted to the National Cancer Institute (NCI), National Institutes of Health (NIH), UL TR000124 submitted to the National Center for Advancing Translational Sciences (NCATS), NIH, and P01 AI131294-01, R01 AI126914-01, R21 AI131013-01, R21 AI131451-01, R21 AI131451-01A1, R21 AI142068-01, R43 AI136224-01, R44 AI126960-01, and R44 AI128983-01 submitted to the National Institute of Allergy and Infectious Diseases, NIH.

ORI finds that Respondent engaged in research misconduct by knowingly and recklessly falsifying and/or fabricating flow cytometry data that were included in the following eleven (11) grant applications submitted for PHS funds:

- R43 CA228629-01, "CTL Based Therapeutic Vaccine to Prevent or Interrupt HPV Mediated Oncogenesis," submitted to NCI, NIH, Awarded Project Dates: September 18, 2018-February 29, 2020.

- UL1 TR000124, "UCLA Clinical and Translational Science Institute," submitted to NCATS, NIH, Awarded Project Dates: June 1, 2011-August 31, 2016.

- P01 AI131294-01, "Defining Factors Controlling HIV Rebound," submitted to NIAID, NIH, Awarded Project Dates: August 10, 2017-July 31, 2022.

- R01 AI126914-01, "A Recombinant Human Vault CTL-Based HIV Vaccine Component," submitted to NIAID, NIH, on December 23, 2015.

- R21 AI131013-01, "A Novel Cellular Immune Zika Vaccine," submitted to NIAID, NIH, on June 14, 2016.

- R21 AI131451-01, "A Novel Therapeutic Vaccine for HPV Oncogenesis," submitted to NIAID, NIH, on June 14, 2016.

- R21 AI131451-01A1, "A Novel Therapeutic Vaccine for HPV Oncogenesis," submitted to NIAID, NIH, on June 13, 2017.

- R21 AI142068-01, "A Novel Therapeutic Vaccine for HPV Oncogenesis," submitted to NIAID, NIH, on February 12, 2018.

- R43 AI136224-01, "Development of A Novel Pan-Serovar Vaccine for Chlamydia," submitted to NIAID, NIH, on April 5, 2017.

- R44 AI126960-01, "Novel Pan-Serovar Vaccine for Chlamydia," submitted to NIAID, NIH, on January 4, 2016.

- R44 AI128983-01, "Design of a Novel CTL Retargeting Therapeutic HIV Vaccine," submitted to NIAID, NIH, on April 2, 2016.

ORI finds that Respondent knowingly and recklessly falsified and/or fabricated flow cytometry data to represent interferon-γ (IFN-γ) expression in immune cells of mice administered with human recombinant vaults such that the represented data were incompatible with the raw experimental data. Specifically, Respondent falsified and/or fabricated flow cytometry data to represent:

- IFN-γ expression in the immune cells of mice injected subcutaneously or intranasally with human recombinant vaults containing HIV Gag peptides such that the vaccinated arm of the experiment showed antigen-specific T-cell responses in:

  - Figure 6 of UL1 TR000124
  - Figure 2 of R43 CA228629
  - Figure 8 of R21 AI131451-01
  - Figure 9 of R21 AI131451-01A1
  - Figure 9 of R44 AI126960-01
  - Figure 3 of R43 AI136224-01
  - Figure 9 of R21 AI131013
  - Figure 7 of R01 AI126914
  - Figure 7 of R44 AI128983
  - Figures 8A and 8B of R21 AI142068-01

- increased IFN-γ expression in the immune cells of mice injected with human recombinant vaults containing HPV peptides in Figure 3 of R43 CA228629

- dose-dependent increase in IFN-γ expression in the immune cells of mice injected with human recombinant vaults containing HIV Gag peptides in Figure 8 of P01 AI131294 and Figure 8C of R21 AI142068-01

- IFN-γ expression in the immune cells of mice administered intranasally with human recombinant vaults containing HPV peptides in Figure 10 of R21 AI131451-01A1 and Figure 10 of R21 AI142068-01

- IFN-γ expression in the immune cells of mice administered orally with human recombinant vaults containing HIV Gag peptides in Figure 11 of R21 AI131451-01A1 and Figure 9 of R21 AI142068-01

- IFN-γ expression in the immune cells of mice immunized subcutaneously with increasing doses of human recombinant vaults containing HIV Gag-1 spanning peptides in Figure 14 of R01 AI126914 and Figure 13 of R44 AI128983

The Parties wish to conclude this matter without further expenditure of time, finances, or other resources. The Parties therefore agree to the following terms:

1. Respondent will not contest or appeal the ORI findings of research misconduct as set forth above.

2. Respondent will not contest or appeal the jurisdiction of ORI in this matter.

3. Respondent will have her research supervised for a period of three (3) years beginning with the effective date of this Agreement (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.

4. The requirements for Respondent's supervision plan are as follows:

    i. A committee of 2 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 three (3) years from the effective date of this Agreement. The committee will review Respondent'sprimary data 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 Respondent's research. 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 Respondent's data presented in the proposed application, report, manuscript, or abstract are supported by the research record.

5. 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 in the application, report, manuscript, or abstract.

6. 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.

7. 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.

8. Paragraphs 1 through 7 are material provisions of this Agreement. A violation of any of these material provisions, as determined by ORI after providing Respondent with notice of the alleged violation and an opportunity to respond in writing, constitutes sufficient cause for HHS to exclude Respondent pursuant to 2 C.F.R. Parts 180 and 376 (collectively "the Debarment Regulations"). ORI's determination of Respondent's violation is unappealable. If ORI determines Respondent violated this Agreement, Respondent will: (1) voluntarily exclude herself from any contracting or subcontracting with any agency of the U.S. Government and from eligibility for or involvement in nonprocurement and procurement transactions referred to as "covered transactions" in the Debarment Regulations; and (2) voluntarily exclude herself from serving in any advisory or consultant capacity to the PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee. The period of such voluntary exclusion will begin when ORI notifies Respondent of its determination and will be equal to the duration of the violation plus one year. During the period of such voluntary exclusion, Respondent will not apply for, permit her name to be used on an application for, receive, or be supported by funds of the United States Government and its agencies made available through contracts, subcontracts, or covered transactions. HHS will enter the voluntary exclusion in the General Services Administration's System for Award Management (SAM), and ORI will publish a notice of the determination of a violation of this Agreement and Respondent's exclusion in the *Federal Register*.

9. ORI will close this research misconduct proceeding as of the effective date of this Agreement.

10. In accordance with its normal procedures, ORI will provide public notice of this Agreement in the *Federal Register* and on the ORI website, and Respondent's current institution may be notified if the institution is the recipient of PHS funds. Pursuant to 42 C.F.R. § 93.409, settlement agreements are publicly available.

11. This Agreement will become binding only when it is signed by both Parties and will become effective on the date it is signed by HHS.

12. This Agreement contains the complete description of the understanding between the Parties with respect to the subject matter of this Agreement and supersedes all other agreements between the Parties. Any modifications must be set forth in writing and signed by all Parties. Respondent represents that she enters into this Agreement voluntarily with knowledge of the events described.

(b)(6); (b)(7)(C)

7/18/2022
Date

Janina Jiang, M.D., Ph.D., Respondent

(b)(6); (b)(7)(C)

07/22/2022
Date

Principal Deputy Assistant Secretary for Health
Office of the Assistant Secretary for Health
U.S. Department of Health and Human Services

From: (b)(6); (b)(7)(C)
To:
Cc: Runko, Alexander (HHS/OASH); Jones, Wanda K. (DHHS/OS/OASH); (b)(6); (b)(7)(C) (HHS/OASH)
Subject: RE: VSA for ORI 2022-12
Date: Friday, July 22, 2022 11:32:46 AM
Attachments: SIGNED - Transmittal Memo to PDASH for Proposed Voluntary Settlement Agreement - ORI 2022-12.pdf
SIGNED - TAB A - ORI 2022-12 VSA.pdf

Good Morning (b)(6); (b)(7)(C)

The attached package has been approved and signed.

Have a great weekend!

(b)(6); (b)(7)(C)

Office of Research Integrity

Emai (b)(6); (b)(7)(C)

Desk: (b)(6); (b)(7)(C)

From: (b)(6); (b)(7)(C)
Sent: Tuesday, July 19, 2022 4:34 PM
To (b)(6); (b)(7)(C)
Cc: Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C) @hhs.gov>; Jones, Wanda K. (DHHS/OS/OASH) (b)(6); (b)(7)(C)
(b)(6); (b)(7)(C)
Subject: RE: VSA for ORI 2022-12

Thanks very much (b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

From (b)(6); (b)(7)(C)
Sent: Tuesday, July 19, 2022 4:05 PM
To (b)(6); (b)(7)(C)
Cc: Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C) Jones, Wanda K. (DHHS/OS/OASH) (b)(6); (b)(7)(C)
(b)(6); (b)(7)(C)
Subject: RE: VSA for ORI 2022-12

Hi Karen,

Files have been uploaded in SPS for PDASH signature. The case number is (b)(6); (b)(7)(C)
(b)(6); (b)(7)(C)

Office of Research Integrity

Email (b)(6); (b)(7)(C)
Desk: (b)(6); (b)(7)(C)

<< OLE Object: Picture (Device Independent Bitmap) >>

From (b)(6); (b)(7)(C)
Sent: Tuesday, July 19, 2022 3:14 PM
To (b)(6); (b)(7)(C)
Cc: Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C) Jones, Wanda K. (DHHS/OS/OASH) (b)(6); (b)(7)(C)
(b)(6); (b)(7)(C)
Subject: VSA for ORI 2022-12

<< File: Transmittal Memo to PDASH for Proposed Voluntary Settlement Agreement - ORI 2022-12.pdf >> << File: TAB A - ORI 2022-12 VSA.pdf >>

Hi (b)(6); (b)(7)(C)

Please upload the attached transmittal memo to the PDASH and the VSA (TAB A) in SPS for Lis' signature. Lis sent us an email letting us know that she can sign this one (b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

Thanks very much,

(b)(6); (b)(7)(C)

Division of Investigative Oversight

Office of Research Integrity

Email: (b)(6); (b)(7)(C)

Desk:

<< OLE Object: Picture (Device Independent Bitmap) >>

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Assistant Secretary for Health
Office of Research Integrity
1101 Wootton Parkway, Suite 240
Rockville, MD, 20852

Phone: 240-453-8200
FAX: 301-594-0043

DATE: July 19, 2022

TO: Elisabeth A. Handley
Principal Deputy Assistant Secretary for Health (PDASH)
Office of the Assistant Secretary for Health
U.S. Department of Health and Human Services

FROM: Acting Director
Office of Research Integrity

SUBJECT: Proposed Voluntary Settlement Agreement for ORI 2022-12

ISSUE

The Office of Research Integrity (ORI) has received the attached signed Voluntary Settlement Agreement (Agreement) (Tab A) from Janina Jiang, M.D., Ph.D. (Respondent), who was an Assistant Researcher in the Department of Pathology & Laboratory Medicine at the David Geffen School of Medicine, University of California, Los Angeles (UCLA). ORI requests that you approve the administrative actions set forth in the Agreement as discussed below.

DISCUSSION

Based on the report of an investigation conducted by UCLA and additional analysis conducted by ORI in its oversight review, ORI finds that Respondent engaged in research misconduct in research included in grant applications submitted for U.S. Public Health Service (PHS) funds, specifically R43 CA228629-01 submitted to the National Cancer Institute (NCI), National Institutes of Health (NIH), UL1 TR000124 submitted to the National Center for Advancing Translational Sciences (NCATS), NIH, and P01 AI131294-01, R01 AI126914-01, R21 AI131013-01, R21 AI131451-01, R21 AI131451-01A1, R21 AI142068-01, R43 AI136224-01, R44 AI126960-01, and R44 AI128983-01 submitted to the National Institute of Allergy and Infectious Diseases (NIAID), NIH.

The terms of the Agreement include the following:

1. Respondent will not contest or appeal the ORI findings of research misconduct as set forth in the Agreement.

2. Respondent will not contest or appeal the jurisdiction of ORI in this matter.

3. Respondent will have her research supervised for a period of three (3) years beginning with the effective date of this Agreement (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.

4. The requirements for Respondent's supervision plan are as follows:

    i. A committee of two 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 three (3) years from the effective date of this Agreement. The committee will review Respondent's primary data 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 Respondent's research. 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 Respondent's data presented in the proposed application, report, manuscript, or abstract are supported by the research record.

5. 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 in the application, report, manuscript, or abstract.

6. 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.

7. 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.

The research misconduct findings and administrative actions are described in greater detail in the attached Agreement.

RECOMMENDATION

ORI recommends that you approve the Agreement. If you agree, please sign the Agreement and return it to my attention. We will then forward a fully executed copy to the Respondent and arrange for the other usual notifications.

ORI staff would be glad to meet with you and discuss the proposed settlement and background materials. If you prefer a more in-depth presentation of the science involved, (b)(6); (b)(7)(C) Scientist-Investigator, Division of Investigative Oversight, ORI, who performed the analysis for ORI's oversight review, is available to make a presentation.

DECISIONS

Approved (b)(6); (b)(7)(C) Disapproved _____ Date 07/22/2022

Wanda K. Jones, DrPH, MT(ASCP)

Digitally signed by Wanda K. Jones, DrPH, MT(ASCP)
Date: 2022.07.19 15:02:45 -04'00'

Wanda K. Jones, Dr.P.H.

Attachment
Tab A: Voluntary Settlement Agreement

cc: Assistant Secretary for Health (without attachment)

VOLUNTARY SETTLEMENT AGREEMENT

This Voluntary Settlement Agreement (Agreement) is entered into by and between the United States Department of Health and Human Services (HHS) and Janina Jiang, M.D., Ph.D., (Respondent) (collectively, "the Parties").

The purpose of this Agreement is to settle the HHS Office of Research Integrity's (ORI's) research misconduct proceeding against Respondent, who was an Assistant Researcher in the Department of Pathology & Laboratory Medicine at the David Geffen School of Medicine, University of California, Los Angeles (UCLA).

Based on the report of an investigation conducted by UCLA and additional analysis conducted by ORI in its oversight review, ORI finds that Respondent engaged in research misconduct in research included in grant applications submitted for U.S. Public Health Service (PHS) funds, specifically R43 CA228629-01 submitted to the National Cancer Institute (NCI), National Institutes of Health (NIH), UL TR000124 submitted to the National Center for Advancing Translational Sciences (NCATS), NIH, and P01 AI131294-01, R01 AI126914-01, R21 AI131013-01, R21 AI131451-01, R21 AI131451-01A1, R21 AI142068-01, R43 AI136224-01, R44 AI126960-01, and R44 AI128983-01 submitted to the National Institute of Allergy and Infectious Diseases, NIH.

ORI finds that Respondent engaged in research misconduct by knowingly and recklessly falsifying and/or fabricating flow cytometry data that were included in the following eleven (11) grant applications submitted for PHS funds:

- R43 CA228629-01, "CTL Based Therapeutic Vaccine to Prevent or Interrupt HPV Mediated Oncogenesis," submitted to NCI, NIH, Awarded Project Dates: September 18, 2018-February 29, 2020.

- UL1 TR000124, "UCLA Clinical and Translational Science Institute," submitted to NCATS, NIH, Awarded Project Dates: June 1, 2011-August 31, 2016.

- P01 AI131294-01, "Defining Factors Controlling HIV Rebound," submitted to NIAID, NIH, Awarded Project Dates: August 10, 2017-July 31, 2022.

- R01 AI126914-01, "A Recombinant Human Vault CTL-Based HIV Vaccine Component," submitted to NIAID, NIH, on December 23, 2015.

- R21 AI131013-01, "A Novel Cellular Immune Zika Vaccine," submitted to NIAID, NIH, on June 14, 2016.

- R21 AI131451-01, "A Novel Therapeutic Vaccine for HPV Oncogenesis," submitted to NIAID, NIH, on June 14, 2016.

- R21 AI131451-01A1, "A Novel Therapeutic Vaccine for HPV Oncogenesis," submitted to NIAID, NIH, on June 13, 2017.

- R21 AI142068-01, "A Novel Therapeutic Vaccine for HPV Oncogenesis," submitted to NIAID, NIH, on February 12, 2018.

- R43 AI136224-01, "Development of A Novel Pan-Serovar Vaccine for Chlamydia," submitted to NIAID, NIH, on April 5, 2017.

- R44 AI126960-01, "Novel Pan-Serovar Vaccine for Chlamydia," submitted to NIAID, NIH, on January 4, 2016.

- R44 AI128983-01, "Design of a Novel CTL Retargeting Therapeutic HIV Vaccine," submitted to NIAID, NIH, on April 2, 2016.

ORI finds that Respondent knowingly and recklessly falsified and/or fabricated flow cytometry data to represent interferon-γ (IFN-γ) expression in immune cells of mice administered with human recombinant vaults such that the represented data were incompatible with the raw experimental data. Specifically, Respondent falsified and/or fabricated flow cytometry data to represent:

- IFN-γ expression in the immune cells of mice injected subcutaneously or intranasally with human recombinant vaults containing HIV Gag peptides such that the vaccinated arm of the experiment showed antigen-specific T-cell responses in:

  - Figure 6 of UL1 TR000124
  - Figure 2 of R43 CA228629
  - Figure 8 of R21 AI131451-01
  - Figure 9 of R21 AI131451-01A1
  - Figure 9 of R44 AI126960-01
  - Figure 3 of R43 AI136224-01
  - Figure 9 of R21 AI131013
  - Figure 7 of R01 AI126914
  - Figure 7 of R44 AI128983
  - Figures 8A and 8B of R21 AI142068-01

- increased IFN-γ expression in the immune cells of mice injected with human recombinant vaults containing HPV peptides in Figure 3 of R43 CA228629

- dose-dependent increase in IFN-γ expression in the immune cells of mice injected with human recombinant vaults containing HIV Gag peptides in Figure 8 of P01 AI131294 and Figure 8C of R21 AI142068-01

- IFN-γ expression in the immune cells of mice administered intranasally with human recombinant vaults containing HPV peptides in Figure 10 of R21 AI131451-01A1 and Figure 10 of R21 AI142068-01

- IFN-γ expression in the immune cells of mice administered orally with human recombinant vaults containing HIV Gag peptides in Figure 11 of R21 AI131451-01A1 and Figure 9 of R21 AI142068-01

- IFN-γ expression in the immune cells of mice immunized subcutaneously with increasing doses of human recombinant vaults containing HIV Gag-1 spanning peptides in Figure 14 of R01 AI126914 and Figure 13 of R44 AI128983

The Parties wish to conclude this matter without further expenditure of time, finances, or other resources. The Parties therefore agree to the following terms:

1. Respondent will not contest or appeal the ORI findings of research misconduct as set forth above.

2. Respondent will not contest or appeal the jurisdiction of ORI in this matter.

3. Respondent will have her research supervised for a period of three (3) years beginning with the effective date of this Agreement (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.

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6. 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.

7. 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.

8. Paragraphs 1 through 7 are material provisions of this Agreement. A violation of any of these material provisions, as determined by ORI after providing Respondent with notice of the alleged violation and an opportunity to respond in writing, constitutes sufficient cause for HHS to exclude Respondent pursuant to 2 C.F.R. Parts 180 and 376 (collectively "the Debarment Regulations"). ORI's determination of Respondent's violation is unappealable. If ORI determines Respondent violated this Agreement, Respondent will: (1) voluntarily exclude herself from any contracting or subcontracting with any agency of the U.S. Government and from eligibility for or involvement in nonprocurement and procurement transactions referred to as "covered transactions" in the Debarment Regulations; and (2) voluntarily exclude herself from serving in any advisory or consultant capacity to the PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee. The period of such voluntary exclusion will begin when ORI notifies Respondent of its determination and will be equal to the duration of the violation plus one year. During the period of such voluntary exclusion, Respondent will not apply for, permit her name to be used on an application for, receive, or be supported by funds of the United States Government and its agencies made available through contracts, subcontracts, or covered transactions. HHS will enter the voluntary exclusion in the General Services Administration's System for Award Management (SAM), and ORI will publish a notice of the determination of a violation of this Agreement and Respondent's exclusion in the *Federal Register*.

9. ORI will close this research misconduct proceeding as of the effective date of this Agreement.

10. In accordance with its normal procedures, ORI will provide public notice of this Agreement in the *Federal Register* and on the ORI website, and Respondent's current institution may be notified if the institution is the recipient of PHS funds. Pursuant to 42 C.F.R. § 93.409, settlement agreements are publicly available.

11. This Agreement will become binding only when it is signed by both Parties and will become effective on the date it is signed by HHS.

12. This Agreement contains the complete description of the understanding between the Parties with respect to the subject matter of this Agreement and supersedes all other agreements between the Parties. Any modifications must be set forth in writing and signed by all Parties. Respondent represents that she enters into this Agreement voluntarily with knowledge of the events described.

(b)(6); (b)(7)(C)

7/18/2022
Date

Janina Jiang, M.D., Ph.D., Respondent

(b)(6); (b)(7)(C)

07/22/2022
Date

Principal Deputy Assistant Secretary for Health
Office of the Assistant Secretary for Health
U.S. Department of Health and Human Services

From: Runko, Alexander (HHS/OASH)
To: (b)(6); (b)(7)(C)
Subject: RE: ORI 2022-12 PDASH Memo and VSA
Date: Tuesday, July 19, 2022 2:39:00 PM
Attachments: Transmittal Memo to PDASH for Proposed Voluntary Settlement Agreement - ORI 2022-12 (b)(6); AR.doc

I made one more edit in the same section.

From: (b)(6); (b)(7)(C)
Sent: Tuesday, July 19, 2022 2:38 PM
To: (b)(6); (b)(7)(C) @hhs.gov>; Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C) @hhs.gov>
Subject: RE: ORI 2022-12 PDASH Memo and VSA

Thanks (b)(6); (b)(7)(C) Alex! I'll send to Wanda shortly.

(b)(6); (b)(7)(C)

From: (b)(6); (b)(7)(C)
Sent: Tuesday, July 19, 2022 2:34 PM
To: Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C) (b)(6); (b)(7)(C)
Subject: RE: ORI 2022-12 PDASH Memo and VSA

Hi (b)(6); (b)(7)(C) Alex,

I made a change in the memo, (b)(6); (b)(7)(C) to reflect the change we made in VSA based on respondent's request. (b)(6); (b)(7)(C) (b)(6); (b)(7)(C)

Thanks
(b)(6); (b)(7)(C)

From: Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C)
Sent: Tuesday, July 19, 2022 2:22 PM
To: (b)(6); (b)(7)(C) (b)(6); (b)(7)(C)
Subject: RE: ORI 2022-12 PDASH Memo and VSA

Thanks. I made one correction in the memo and VSA. (b)(6); (b)(7)(C) (b)(6); (b)(7)(C)

From: (b)(6); (b)(7)(C)
Sent: Tuesday, July 19, 2022 2:11 PM
To: Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C) (HHS/OASH)
(b)(6); (b)(7)(C)
Subject: ORI 2022-12 PDASH Memo and VSA
Importance: High

<< File: Transmittal Memo to PDASH for Proposed Voluntary Settlement Agreement - ORI 2022-12.doc >> << File: TAB A - ORI 2022-12 VSA.pdf >>
Hi Alex (b)(6);

Here's the transmittal to the PDASH for your review. It looks like if we can get this to Lis today or tomorrow, she'll sign the VSA this week. If it looks okay to both of you, I'll send it to Wanda for signature this afternoon and then to (b)(6); so she can upload it in SPS for Lis' signature.

Thanks,

(b)(6); (b)(7)(C)
Division of Investigative Oversight
Office of Research Integrity

Email: (b)(6); (b)(7)(C)
Desk:

<< OLE Object: Picture (Device Independent Bitmap) >>

Page 201 to Page 203

Withheld pursuant to exemption

(b)(5)

of the Freedom of Information Act

From: (b)(6); (b)(7)(C)
To: Runko, Alexander (HHS/OASH); (b)(6); (HHS/OASH)
Subject: RE: ORI 2022-12 PDASH Memo and VSA
Date: Tuesday, July 19, 2022 2:35:29 PM
Attachments: Transmittal Memo to PDASH for Proposed Voluntary Settlement Agreement - ORI 2022-12 (b)(6); (b)(7)(C

Hi (b)(6); (b)(7)(and Alex,

I made a change in the memo, (b)(6); to reflect the change we made in VSA based on respondent's request. (b)(6); (b)(7)(C)
(b)(6); (b)(7)(C)

Thanks
(b)(6);
(b)(7)(C)

From: Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C)
Sent: Tuesday, July 19, 2022 2:22 PM
To: Gorirossi, Karen (HHS/OASH) (b)(6); (b)(7)(C)
(b)(6); (b)(7)(C)
Subject: RE: ORI 2022-12 PDASH Memo and VSA

Thanks, I made one correction in the memo and VSA. (b)(6); (b)(7)(C)
(b)(6); (b)(7)(C)

From: (b)(6); (b)(7)(C)
Sent: Tuesday, July 19, 2022 2:11 PM
To: Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C)
(b)(6); (b)(7)(C)
Subject: ORI 2022-12 PDASH Memo and VSA
Importance: High

<< File: Transmittal Memo to PDASH for Proposed Voluntary Settlement Agreement - ORI 2022-12.doc >> << File: TAB A - ORI 2022-12 VSA.pdf >>
Hi Alex (b)(6); (b)(7)(C)

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Thanks,
(b)(6);
(b)(7)(C

(b)(6); (b)(7)(C)

Division of Investigative Oversight
Office of Research Integrity

Email: (b)(6); (b)(7)(C)
Desk:

<< OLE Object: Picture (Device Independent Bitmap) >>

Page 206 to Page 208

Withheld pursuant to exemption

(b)(5)

of the Freedom of Information Act

From: Runko, Alexander (HHS/OASH)
To: (b)(6); (b)(7)(C) HHS/OASH)
Subject: RE: ORI 2022-12 PDASH Memo and VSA
Date: Tuesday, July 19, 2022 2:22:00 PM
Attachments: Transmittal Memo to PDASH for Proposed Voluntary Settlement Agreement - ORI 2022-12.doc
TAB A - ORI 2022-12 VSA.pdf

Thanks, I made one correction in the memo and VSA. (b)(6); (b)(7)(C)
(b)(6); (b)(7)(C)

From: (b)(6); (b)(7)(C)
Sent: Tuesday, July 19, 2022 2:11 PM
To: Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C)
(b)(6); (b)(7)(C)
Subject: ORI 2022-12 PDASH Memo and VSA
Importance: High

<< File: Transmittal Memo to PDASH for Proposed Voluntary Settlement Agreement - ORI 2022-12.doc >> << File: TAB A - ORI 2022-12 VSA.pdf >>
Hi Alex (b)(6); (b)(7)(C)

Here's the transmittal to the PDASH for your review. It looks like if we can get this to Lis today or tomorrow, she'll sign the VSA this week. If it looks okay to both of you, I'll send it to Wanda for signature this afternoon and then to (b)(6); so she can upload it in SPS for Lis' signature.

Thanks,

(b)(6); (b)(7)(C)
Division of Investigative Oversight
Office of Research Integrity

Email: (b)(6); (b)(7)(C)
Desk:

<< OLE Object: Picture (Device Independent Bitmap) >>

Page 210 to Page 218

Withheld pursuant to exemption

(b)(5)

of the Freedom of Information Act

From: (b)(6); (b)(7)(C)
To: Runko, Alexander (HHS/OASH); (b)(6); (b)(7)(C)
Subject: ORI 2022-12 PDASH Memo and VSA
Date: Tuesday, July 19, 2022 2:13:00 PM
Attachments: Transmittal Memo to PDASH for Proposed Voluntary Settlement Agreement - ORI 2022-12.doc
TAB A - ORI 2022-12 VSA.pdf
Importance: High

Hi Alex (b)(6); (b)(7)(C)

Here's the transmittal to the PDASH for your review. It looks like if we can get this to Lis today or tomorrow, she'll sign the VSA this week. If it looks okay to both of you, I'll send it to Wanda for signature this afternoon and then to (b)(6); (b)(7)(C) so she can upload it in SPS for Lis' signature.

Thanks,

(b)(6); (b)(7)(C)

Division of Investigative Oversight

Office of Research Integrity

Ema (b)(6); (b)(7)(C)

Desk

Page 220 to Page 228

Withheld pursuant to exemption

(b)(5)

of the Freedom of Information Act

From: Janina Jiang
To: Runko, Alexander (HHS/OASH)
Cc: (b)(6); (b)(7)(C)
Subject: Re: ORI 2022-12 revised VSA
Date: Tuesday, July 19, 2022 2:55:55 AM
Attachments: (b)(6); (b)(7)(C)
ORI 2022-12 VSA 07-15-2022 revised (1).pdf

Dear Runko,

Attached please find signed docs.

Best,
Janina

On Mon, Jul 18, 2022 at 1:29 PM Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C) wrote:

> It applies to the data present in the manuscript that was funded by PHS (NIH), or if the data appears in a proposal for PHS funding.
>
> **From:** Janina Jiang (b)(6); (b)(7)(C)
> **Sent:** Monday, July 18, 2022 4:21 PM
> **To:** Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C)
> **Cc:** (b)(6); (b)(7)(C)
> **Subject:** Re: ORI 2022-12 revised VSA
>
> Hi Dr. Runko,
>
> Just like to confirm that all these apply to PHS funded projects only, do I have this correct? Thanks!
>
> Best,
>
> Janina
>
> Sent from my iPhone

On Jul 18, 2022, at 12:17 PM, Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C) wrote:

Janina,

Below are the clarifying answers in response to your questions:

1. ORI can provide that statement to your institutional RIO when the VSA becomes finalized (once it is signed by you and the authorized HHS official).
2. The supervisory committee must review your PHS-supported work in the manuscript before it is submitted to the journal, and provide a certification to ORI that your data was legitimately derived and represented. Your committee will work with you if there are any questions or ambiguity about your research. ORI will review the certification and if needed, ask for further information.
3. The supervision period will become final after (b)(6); (b)(7)(years from the effective date of the VSA. (b)(6); (b)(7)(C) (b)(6); (b)(7)(C)

Let me know if you have any further questions.

-Alex

From: Janina Jiang (b)(6); (b)(7)(C)
Sent: Monday, July 18, 2022 2:44 PM
To: Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C)
Cc: (b)(6); (b)(7)(C)
Subject: Re: ORI 2022-12 revised VSA

Dear Dr. Runko,

Thank you so much for your cooperation on finalizing VSA. Here are a couple of points I would like to clarify before signing it:

1. Can you send the statement in your earlier corresponding email (shown

below) to my institute counterpart who will execute this matter.

(b)(6); (b)(7)(C)

(b)(6); (b)(7)(C) how to execute it practically: (b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

Thanks, looking forward to your responses!

Best,

Janina

Sent from my iPhone

On Jul 15, 2022, at 1:39 PM, Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C) wrote:

I have revised (b)(6); (b)(7)(C) to two members (attached). It is not possible to remove (b)(6); as it is part of the federal regulations and ORI policy. (b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

From: Janina Jiang <(b)(6); (b)(7)(C)
Sent: Friday, July 15, 2022 4:23 PM
To: Runko, Alexander (HHS/OASH)
(b)(6); (b)(7)(C)
Cc: (b)(6); (b)(7)(C)
Subject: Re: ORI 2022-12 revised VSA

Thanks Dr. Runko,

Also can we (b)(6); (b)(7)(C)
(b)(6); (b)(7)(C)
(b)(6); (b)(7)(C) hanks.

Best,

Janina

Sent from my iPhone

> On Jul 15, 2022, at 12:17 PM, Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C) > wrote:
>
> I have revised (b)(6); (b)(7)(C) o incorporate your requested changes – please see the attached.
>
> **From:** Janina Jiang <(b)(6); (b)(7)(C)
> **Sent:** Friday, July 15, 2022 3:07 PM
> **To:** Runko, Alexander (HHS/OASH)
> (b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

Subject: Re: ORI 2022-12 revised VSA

Thank you Dr. Runko! It's quite clear in you email. Can we articulate it into the revised VSA: (b)(6); (b)(7)(

(b)(6); (b)(7)(C)

(b)(6); (b)(7)(C) Thanks!

Best,

Janina

Sent from my iPhone

> On Jul 15, 2022, at 11:39 AM, Runko, Alexander (HHS/OASH) <(b)(6); (b)(7)(C)> wrote:
>
> Hi Janina,
>
> Thanks for your reply. To answer your questions, the requirements of the supervision plan gives some latitude to the institution conducting the supervision. (b)(6);
>
> (b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

hope that this answers your questions.

-Alex

From: Janina Jiang
(b)(6); (b)(7)(C)
Sent: Friday, July 15, 2022 2:16 PM
To: Runko, Alexander (HHS/OASH)
(b)(6); (b)(7)(C)
Subject: Re: ORI 2022-12 revised VSA

Hi Dr. Runko,

Here are some questions about VSA:
(b)(6); (b)(7)(C)

(b)(6); (b)(7)(C) I was not clear from our conversations! Please advise! Thanks!

Best,

Janina

Sent from my iPhone

On Jul 15, 2022, at 8:23 AM, Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C) > wrote:

Dear Janina,

(b)(6); (b)(7)(C)

In order to reconcile this case with ORI, you can sign the VSA now so that you may continue to conduct research with PHS (NIH) funds without delay. (b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

ORI has an obligation to

protect PHS research funds and the integrity of that funded research. ORI is required to adhere to the federal regulations at 42 C.F.R. Part 93, and we have our own policies, procedures, and timelines to abide by.

(b)(6); (b)(7)(C)

(b)(6); (b)(7)(C) If ORI does not receive your signature on the VSA by that date, we would have no other recourse than to contact the Research Integrity Officer (RIO) at your current institution at this time in order to preserve the integrity of PHS-funded research and to safeguard those PHS funds.

Under our regulatory authority at § 93.409(a), ORI may settle a research misconduct proceeding at any time that it concludes that the settlement is in the best interests of the Federal government and the public health or welfare. (b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

(b)(6); (b)(7)(C) in accordance with § 93.405.

(b)(6); (b)(7)(C)

(b)(6); (b)(7)(C) As

prescribed in § 93.501, you would have the opportunity to contest ORI findings of research misconduct and HHS administrative actions by requesting an administrative hearing before an Administrative Law Judge (ALJ).

ORI anticipates that we can achieve an amicable resolution of this matter by receiving the VSA with your signature by Monday (enclosed). If you need additional information, please contact me, (b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

Best,

Alex

Alexander Runko, Ph.D.

Director, Division of Investigative Oversight
Office of Research Integrity

Email: (b)(6); (b)(7)(C)

Office: (240) 453-8800

Desk: (b)(6); (b)(7)(C)

ori.hhs.gov/

OASH | Office of Research Integrity

From: Janina Jiang (b)(6); (b)(7)(C)
Sent: Friday, July 15, 2022 2:57 AM
To: Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C)
(b)(6); (b)(7)(C)
Subject: Re: ORI 2022-12 revised VSA

Dear Dr. Runko,

(b)(6); (b)(7)(C)

Meanwhile, I greatly appreciate your understanding. Thank you so much!

Best,

Janina

On Fri, Jul 8, 2022 at 7:23 AM Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C) wrote:

Dear Dr. Jiang,

Please let me know if you or your supervisor require any additional information or have questions regarding the terms of the voluntary settlement agreement (VSA) or the supervision plan. We look forward in your continuing cooperation to settle this matter with the revised VSA. Once you sign it, please return the VSA to ORI promptly so that it can be signed by the authorized HHS Official, and then the VSA and supervision plan will become effective.

Best,

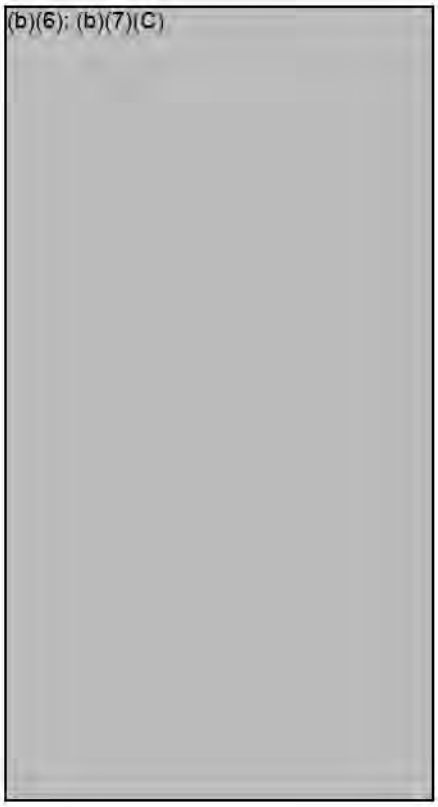
Alex

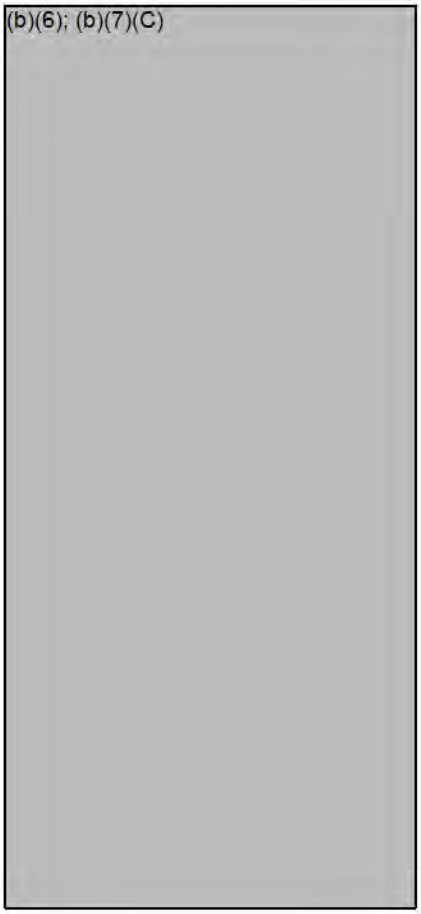
From: Runko, Alexander (HHS/OASH)
Sent: Thursday, June 30, 2022 6:10 PM
To: (b)(6); (b)(7)(C)
(b)(6); (b)(7)(C)

Subject: ORI 2022-12
revised VSA

Dear Dr. Jiang,

Thanks for speaking with us today, we heard your explanations and concerns, and appreciate the time that you have taken in cooperating to come to an agreement to settle this matter. As discussed, enclosed is the voluntary supervision agreement (VSA) with the revisions, and below are the statements from ORI that you can share with your supervisor. Please do not hesitate to contact us with additional questions, or if your supervisor would like to schedule a call with us.





Best,

Alex

Alexander Runko, Ph.D.

Director, Division of
Investigative Oversight
Office of Research Integrity

Email: (b)(6); (b)(7)(C)

Office: (240) 453-8800

Desk: (b)(6); (b)(7)(C)


OASH
Office of
Research Integrity

Page 243 to Page 247

Withheld pursuant to exemption

(b)(5)

of the Freedom of Information Act

From: Runko, Alexander (HHS/OASH)
To: Janina Jiang
Cc: (b)(6); (b)(7)(C)
Subject: RE: ORI 2022-12 revised VSA
Date: Friday, July 15, 2022 4:39:00 PM
Attachments: image001.png
image002.png
ORI 2022-12 VSA 07-15-2022 revised.pdf

I have revised (b)(6); (b)(7)(C) to two members (attached). It is not possible to remove (b)(6); (b)(7)(C) as it is part of the federal regulations and ORI policy. (b)(6); (b)(7)(C)
(b)(6); (b)(7)(C)

From: Janina Jiang (b)(6); (b)(7)(C)
Sent: Friday, July 15, 2022 4:23 PM
To: Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C)
Cc: (b)(6); (b)(7)(C)
Subject: Re: ORI 2022-12 revised VSA

Thanks Dr. Runko,

Also can we 1. (b)(6); (b)(7)(C)
(b)(6); (b)(7)(C)
(b)(6); (b)(7)(C) Thanks.

Best,
Janina

Sent from my iPhone

> On Jul 15, 2022, at 12:17 PM, Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C) wrote:
>
> I have revised (b)(6); (b)(7)(C) to incorporate your requested changes – please see the attached.
>
> **From:** Janina Jiang (b)(6); (b)(7)(C)
> **Sent:** Friday, July 15, 2022 3:07 PM
> **To:** Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C)
> **Cc:** (b)(6); (b)(7)(C)
> **Subject:** Re: ORI 2022-12 revised VSA
>
> Thank you Dr. Runko! It's quite clear in you email. Can we articulate it into the revised

VSA: (b)(6); (b)(7)(C)
(b)(6); (b)(7)(C) Thanks!

Best,
Janina

Sent from my iPhone

On Jul 15, 2022, at 11:39 AM, Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C) wrote:

Hi Janina,

Thanks for your reply. To answer your questions, the requirements of the supervision plan gives some latitude to the institution conducting the supervision. (b)(6); (b)(7)(C)
(b)(6); (b)(7)(C)
(b)(6); (b)(7)(C) I hope that this answers your questions.

-Alex

From: Janina Jiang (b)(6); (b)(7)(C)
Sent: Friday, July 15, 2022 2:16 PM
To: Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C)
Cc: (b)(6); (b)(7)(C)
Subject: Re: ORI 2022-12 revised VSA

Hi Dr. Runko,

Here are some questions about VSA: (b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

(b)(6); (b)(7)(C) I was not clear from our conversations! Please advise! Thanks!

Best,
Janina

Sent from my iPhone

On Jul 15, 2022, at 8:23 AM, Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C) wrote:

Dear Janina,

(b)(6); (b)(7)(C)

In order to reconcile this case with ORI, you can sign the VSA now so that you may continue to conduct research with PHS (NIH) funds without delay. (b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

ORI has an obligation to protect PHS research funds and the integrity of that funded research. ORI is required to adhere to the federal regulations at 42 C.F.R. Part 93, and we have our own policies, procedures, and timelines to abide by. (b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

(b)(6); (b)(7)(C) If ORI does not receive your signature on the VSA by that date, we would have no other recourse than to contact the Research Integrity Officer (RIO) at your current institution at this time in order to preserve the integrity of PHS-funded research and to safeguard those PHS funds.

Under our regulatory authority at § 93.409(a), ORI may settle a research misconduct proceeding at any time that it concludes that the settlement is in the best interests of the Federal government and the public health or welfare. (b)(6); (b)(7)(C) (b)(6); (b)(7)(C) (b)(6); (b)(7)(C) As prescribed in § 93.501, you would have the opportunity to contest ORI findings of research misconduct and HHS administrative actions by requesting an administrative hearing before an Administrative Law Judge (ALJ).

ORI anticipates that we can achieve an amicable resolution of this matter by receiving the VSA with your signature by Monday (enclosed). If you need additional information, please contact me, (b)(6); (b)(7)(C) (b)(6); (b)(7)(C)

Best,
Alex

Alexander Runko, Ph.D.
Director, Division of Investigative Oversight
Office of Research Integrity

Email: (b)(6); (b)(7)(C)
Office: (240) 453-8800
Desk: (b)(6); (b)(7)(C)
ori.hhs.gov/

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From: Janina Jiang (b)(6); (b)(7)(C)
Sent: Friday, July 15, 2022 2:57 AM
To: Runko, Alexander (HHS/OASH)
(b)(6); (b)(7)(C)

Subject: Re: ORI 2022-12 revised VSA

Dear Dr. Runko,

(b)(6); (b)(7)(C)

(b)(6) Meanwhile, I greatly appreciate your understanding. Thank you so much!

Best,
Janina

On Fri, Jul 8, 2022 at 7:23 AM Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C) wrote:

> Dear Dr. Jiang,
>
> Please let me know if you or your supervisor require any additional information or have questions regarding the terms of the voluntary settlement agreement (VSA) or the supervision plan. We look forward in your continuing cooperation to settle this matter with the revised VSA. Once you sign it, please return the VSA to ORI promptly so that it can be signed by the authorized HHS Official, and then the VSA and supervision plan will become effective.
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> Best,
> Alex
>
> **From:** Runko, Alexander (HHS/OASH)
> **Sent:** Thursday, June 30, 2022 6:10 PM
> **To:** (b)(6); (b)(7)(C)
> **Cc:** (b)(6); (b)(7)(C)
> **Subject:** ORI 2022-12 revised VSA
>
> Dear Dr. Jiang,
>
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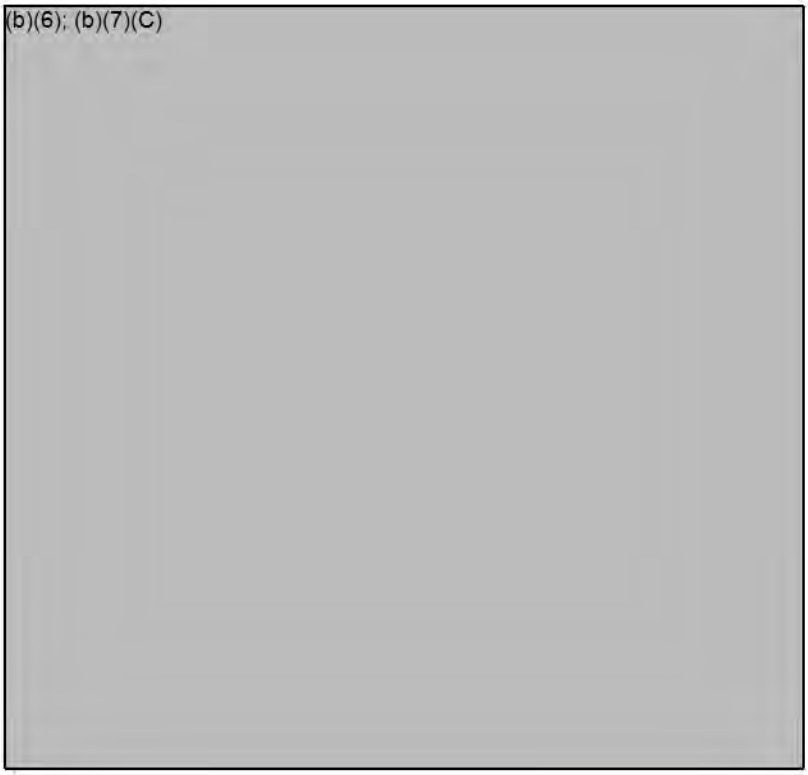
> (b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)



Best,
Alex

Alexander Runko, Ph.D.
Director, Division of Investigative Oversight
Office of Research Integrity

Email: (b)(6); (b)(7)(C)
Office: (240) 453-8800
Desk: (b)(6); (b)(7)(C)
ori.hhs.gov/

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Page 254 to Page 258

Withheld pursuant to exemption

(b)(5)

of the Freedom of Information Act

From: Runko, Alexander (HHS/OASH)
To: Janina Jiang
Cc: (b)(6); (b)(7)(C)
Subject: RE: ORI 2022-12 revised VSA
Date: Friday, July 15, 2022 3:17:00 PM
Attachments: ORI 2022-12 VSA 07-15-2022.pdf
(b)(6); (b)(7)(C)

I have revised (b)(6); (b)(7)(C) to incorporate your requested changes – please see the attached.

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Sent: Friday, July 15, 2022 3:07 PM
To: Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C)
Cc: (b)(6); (b)(7)(C)
Subject: Re: ORI 2022-12 revised VSA

Thank you Dr. Runko! It's quite clear in you email. Can we articulate it into the revised VSA: (b)(6); (b)(7)(C)
(b)(6); (b)(7)(C)
Thanks!

Best,
Janina

Sent from my iPhone

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> (b)(6); (b)(7)(C)

(b)(6); (b)(7)(C) I hope that this answers your questions.

-Alex

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Sent: Friday, July 15, 2022 2:16 PM
To: Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C)
Cc: (b)(6); (b)(7)(C)
Subject: Re: ORI 2022-12 revised VSA

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(b)(6); (b)(7)(C)
(b)(6); (b)(7)(C) I was not clear from our conversations! Please advise! Thanks!

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> (b)(6); (b)(7)(C)
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> (b)(6); (b)(
>
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that funded research. ORI is required to adhere to the federal regulations at 42 C.F.R. Part 93, and we have our own policies, procedures, and timelines to abide by. (b)(6); (b)(7)(C) (b)(6); (b)(7)(C) If ORI does not receive your signature on the VSA by that date, we would have no other recourse than to contact the Research Integrity Officer (RIO) at your current institution at this time in order to preserve the integrity of PHS-funded research and to safeguard those PHS funds.

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Best,
Alex

Alexander Runko, Ph.D.
Director, Division of Investigative Oversight
Office of Research Integrity

Email: (b)(6); (b)(7)(C)
Office: (240) 453-8800
Desk: (b)(6); (b)(7)(C)
ori.hhs.gov/

OASH | Office of Research Integrity

From: Janina Jiang (b)(6); (b)(7)(C)
Sent: Friday, July 15, 2022 2:57 AM
To: Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C)
Cc: (b)(6); (b)(7)(C)
Subject: Re: ORI 2022-12 revised VSA

Dear Dr. Runko,

(b)(6); (b)(7)(C)

(b)(6); (b)(7)(C) Meanwhile, I greatly appreciate your understanding. Thank you so much!

Best,
Janina

On Fri, Jul 8, 2022 at 7:23 AM Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C) wrote:

> Dear Dr. Jiang,
>
> Please let me know if you or your supervisor require any additional information or have questions regarding the terms of the voluntary settlement agreement (VSA) or the supervision plan. We look forward in your continuing cooperation to settle this matter with the revised VSA. Once you sign it, please return the VSA to ORI promptly so that it can be signed by the authorized HHS Official, and then the VSA and supervision plan will become effective.
>
> Best,
> Alex
>
> **From:** Runko, Alexander (HHS/OASH)
> **Sent:** Thursday, June 30, 2022 6:10 PM
> **To** (b)(6); (b)(7)(C)
> **Cc**
> **Subject:** ORI 2022-12 revised VSA
>
> Dear Dr. Jiang,
>
> Thanks for speaking with us today, we heard your explanations and

concerns, and appreciate the time that you have taken in cooperating to come to an agreement to settle this matter. (b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

Best,
Alex

Alexander Runko, Ph.D.
Director, Division of Investigative Oversight
Office of Research Integrity

Email: (b)(6); (b)(7)(C)
Office: (240) 453-8800
Desk: (b)(6); (b)(7)(C)
ori.hhs.gov/

OASH | Office of Research Integrity

Page 264 to Page 268

Withheld pursuant to exemption

(b)(5)

of the Freedom of Information Act

From: (b)(6); (b)(7)(C)
To: Runko, Alexander (HHS/OASH)
Cc: (b)(6); (b)(7)(C)
Subject: Correction notice for Jiang
Date: Monday, September 12, 2022 3:29:03 PM
Attachments: Correction Notice FR Doc 2022-16867 Jiang 09-12-2022.docx

---

Hi Alex,

(b)(6); caught 2 more places in the FRN that need to be changed. See revisions in track changes in the attached doc.

Thanks,

(b)(6); (b)(7)(C)

Division of Investigative Oversight

Office of Research Integrity

Email: (b)(6); (b)(7)(C)

Desk:

Page 270 to Page 271

Withheld pursuant to exemption

(b)(5)

of the Freedom of Information Act

From: Runko, Alexander (HHS/OASH)
To: (b)(6); (b)(7)(C)
Cc:
Subject: ORI 2022-12 revised VSA
Date: Thursday, June 30, 2022 6:10:00 PM
Attachments: ORI 2022-12 (DIO 7163) VSA 06-30-2022.pdf
(b)(6); (b)(7)(C)

Dear Dr. Jiang,

Thanks for speaking with us today, we heard your explanations and concerns, and appreciate the time that you have taken in cooperating to come to an agreement to settle this matter. As discussed, enclosed is the voluntary supervision agreement (VSA) with the revisions, and below are the statements from ORI that you can share with your supervisor. Please do not hesitate to contact us with additional questions, or if your supervisor would like to schedule a call with us.

(b)(6); (b)(7)(C)

Best,
Alex

Alexander Runko, Ph.D.
Director, Division of Investigative Oversight
Office of Research Integrity

Email: (b)(6); (b)(7)(C)
Office: (240) 453-8800
Desk (b)(6); (b)(7)(C)
ori.hhs.gov

OASH | Office of Research Integrity

Page 273 to Page 277

Withheld pursuant to exemption

(b)(5)

of the Freedom of Information Act

From: (b)(6); (HHS/OASH)
To: Runko, Alexander (HHS/OASH)
Subject: RE: DIO 7163 revised VSA
Date: Thursday, June 30, 2022 5:48:53 PM
Attachments: ORI 2022-12 (DIO 7163) VSA 06-30-2022.docx
ORI 2022-12 (DIO 7163) VSA 06-30-2022.pdf

Hi Alex,
Please find attached the revised VSA

Thanks
(b)(6);
(b)(7)(C)

From: Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C)
Sent: Thursday, June 30, 2022 5:35 PM
To: (b)(6); (b)(7)(C)
Subject: FW: DIO 7163

From: Runko, Alexander (HHS/OASH)
Sent: Wednesday, June 15, 2022 2:52 PM
To: (b)(6); (b)(7)(C)
Cc:
Subject: RE: DIO 7163

Thanks (b)(6); I edited one small typo in the letter and VSA.

(b)(6); this can be sent out to both respondent's email addresses. If she is unresponsive after two weeks, then I'll contact the RIO at her new institution to determine whether the respondent is willing to sign.

From: (b)(6); (b)(7)(C)
Sent: Tuesday, June 14, 2022 3:03 PM
To: Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C)
Cc: (b)(6); (b)(7)(C)
Subject: DIO 7163

Hi Alex,

Please find attached the VSA with (b)(6); edits and approach letter. Please see my comments for the respondent address and email and see which ones should we use. The home address was

provided with the investigation report and is from 2020.

Thanks

(b)(6);

<< File: ORI 2022-12 (DIO 7163) VSA with (b)(6); (b)(7)(its.docx >> << File: ORI 2022-12 VSA Approach Letter 06-14-2022.docx >>

Page 280 to Page 290

Withheld pursuant to exemption

(b)(5)

of the Freedom of Information Act

From: (b)(6); (b)(7)(C)
To:
Cc: Runko, Alexander (HHS/OASH); S(b)(6); (b)(7)(C) (HHS/OASH)
Subject: Office of Research Integrity - ORI 2022-12 (DIO 7163)
Date: Thursday, June 16, 2022 11:54:47 AM
Attachments: ORI 2022-12 VSA Approach Letter 06-15-2022.pdf
ORI 2022-12 (DIO 7163) VSA 06-15-2022.pdf

Dear Dr. Jiang,

Please see the attached letter and enclosure to you from Dr. Alexander Runko, Director, Division of Investigative Oversight, Office of Research Integrity, regarding ORI 2022-12 (DIO 7163).

Thank you,

(b)(6); (b)(7)(C)

Division of Investigative Oversight

Office of Research Integrity

Email: (b)(6); (b)(7)(C)

Desk:

Page 292 to Page 299

Withheld pursuant to exemption

(b)(5)

of the Freedom of Information Act

From: Runko, Alexander (HHS/OASH)
To: (b)(6); (b)(7)(C)
Cc:
Subject: RE: DIO 7163
Date: Wednesday, June 15, 2022 2:52:00 PM
Attachments: ORI 2022-12 (DIO 7163) VSA 06-15-2022.docx
ORI 2022-12 (DIO 7163) VSA 06-15-2022.pdf
ORI 2022-12 VSA Approach Letter 06-15-2022.docx
ORI 2022-12 VSA Approach Letter 06-15-2022.pdf

Thanks (b)(6); I edited one small typo in the letter and VSA.

(b)(6); this can be sent out to both respondent's email addresses. If she is unresponsive after two weeks, then I'll contact the RIO at her new institution to determine whether the respondent is willing to sign.

From: (b)(6); (b)(7)(C)
Sent: Tuesday, June 14, 2022 3:03 PM
To: Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C)
Cc: (b)(6); (b)(7)(C)
Subject: DIO 7163

Hi Alex,

Please find attached the VSA with (b)(6); edits and approach letter. Please see my comments for the respondent address and email and see which ones should we use. The home address was provided with the investigation report and is from 2020.

Thanks
(b)(6);

<< File: ORI 2022-12 (DIO 7163) VSA with (b)(6); dits.docx >> << File: ORI 2022-12 VSA Approach Letter 06-14-2022.docx >>

Page 301 to Page 314

Withheld pursuant to exemption

(b)(5)

of the Freedom of Information Act

From: (b)(6); (b)(7)(C)
To: Runko, Alexander (HHS/OASH)
Cc: (b)(6); (b)(7)(C)
Subject: DIO 7163
Date: Tuesday, June 14, 2022 3:03:56 PM
Attachments: ORI 2022-12 (DIO 7163) VSA with (b) edits.docx
ORI 2022-12 VSA Approach Letter 06-14-2022.docx

Hi Alex,

Please find attached the VSA with (b)(6); (b)(7)(C) edits and approach letter. Please see my comments for the respondent address and email and see which ones should we use. The home address was provided with the investigation report and is from 2020.

Thanks

(b)(6);
(b)(7)(C)

Page 316 to Page 322

Withheld pursuant to exemption

(b)(5)

of the Freedom of Information Act

From: Runko, Alexander (HHS/OASH)
To: (b)(6): [redacted] (HHS/OASH)
Subject: RE: DIO 7163 revised
Date: Thursday, June 9, 2022 9:35:00 PM
Attachments: DIO 7163 VSA_V4.docx
Directors memo_misconduct_V2.docx

Hi (b)(6): [redacted]

Thanks for revising the VSA and memo. Please see the attached of my edits and comments. We can discuss this next week if you have questions. If not, it can be sent to (b)(6): (b)(7)(for final review.

-Alex

From: (b)(6); (b)(7)(C) [redacted]
Sent: Wednesday, June 8, 2022 12:56 PM
To: Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C) [redacted]
Subject: DIO 7163 revised

Hi Alex,

Please find attached the revised memo and VSA. I have added the UL1 grant back in the documents and (b)(6); (b)(7)(C) [redacted]

Thanks
(b)(6):
(b)(7)(C) [redacted]

<< File: DIO 7163 VSA_V3.docx >>
<< File: Directors memo_misconduct_V2.docx >>

Page 324 to Page 351

Withheld pursuant to exemption

(b)(5)

of the Freedom of Information Act

From: (b)(6): HHS/OASH)
To: Runko, Alexander (HHS/OASH)
Subject: DIO 7163 revised
Date: Wednesday, June 8, 2022 12:55:54 PM
Attachments: DIO 7163 VSA_V3.docx
Directors memo_misconduct_V2.docx

Hi Alex,

Please find attached the revised memo and VSA. I have added the UL1 grant back in the documents (b)(6): (b)(7)(C)

Thanks

(b)(6):

Page 353 to Page 380

Withheld pursuant to exemption

(b)(5)

of the Freedom of Information Act

From: Runko, Alexander (HHS/OASH)
To: (b)(6); (b)(7)(C)
Subject: RE: DIO7163
Date: Tuesday, May 17, 2022 4:39:00 PM
Attachments: DIO 7163 VSA_AR.docx

Hi (b)(6);

I made it as far as reviewing your VSA, please see the attached. (b)(6); (b)(7)(C)
(b)(6); (b)(7)(C) Hope your trip was enjoyable.

Best,
Alex

From: (b)(6); (b)(7)(C)
Sent: Friday, April 29, 2022 11:25 AM
To: Runko, Alexander (HHS/OASH (b)(6); (b)(7)(C)
Subject: DIO7163

Hi Alex,

Please find the draft VSA and other documents related to 7163 here (b)(6); (b)(7)(C)
(b)(6); (b)(7)(C)

For the misconduct memo, please only see the Institutional investigation and DIO review sections, I have not worked on other sections yet.

I have asked (b)(6); (b)(7)(to assign ORI accession number to the case.

Thanks,
Regards,
(b)(6);
(b)(7)(C

Page 382 to Page 386

Withheld pursuant to exemption

(b)(5)

of the Freedom of Information Act

From: (b)(6); (b)(7)(C)
To:
Cc: Runko, Alexander (HHS/OASH)
Subject: Research Misconduct in NIH grants (DIO7163)
Date: Friday, August 27, 2021 11:17:54 AM

Dear (b)(6); (b)(7)(C)

ORI has received a report of the investigation conducted by University of California, Los Angeles (UCLA) with findings of research misconduct against Dr. Janina Jiang, M.D., Ph.D., former Assistant Researcher in the Department of Pathology & Laboratory Medicine, the David Geffen School of Medicine, UCLA. The DIO accession number associated with this case is DIO 7163. Currently, ORI is conducting its oversight review of the investigation report, however, is informing NIH OER of the findings by the institution as the misconduct deals with data that were used in large number of NIH grant applications, (b)(6); (b)(7)(C) (b)(6); (b)(7)(C)

The institution determined that the data included in the following NIH funded grants were falsified or fabricated:

1. NCATS, NIH Grant UL1 TR000124, (b)(6); (b)(7)(C) (b)(6); (b)(7)(C) Data in Figure 6 were falsified and/or fabricated by reporting immune response results that are incompatible with the raw data files.

2. NCI, SBIR NIH Grant R43 CA228629, CTL Based Therapeutic Vaccine to Prevent or Interrupt HPV Mediated Oncogenesis, (b)(6); (b)(7)(C) Data in Figures 2 and 3 were falsified and/or fabricated by reporting immune response results that are incompatible with the raw data files.

3. NIAID, NIH Grant P01 AI131294, (b)(6); (b)(7)(C) Defining Factors Controlling HIV Rebound, (b)(6); (b)(7)(C) Data in Figure 8 were falsified and/or fabricated by reporting immune response results that are incompatible with the raw data files.

Additionally, the institution determined that the data in the following non-funded grant applications were also falsified or fabricated:

4. NIAID, NIH Grant Application R21 AI131451-01, A Novel Therapeutic Vaccine for HPV Oncogenesis, (b)(6); (b)(7)(C) Data in Figure 8 were falsified and/or fabricated by reporting immune response results that are incompatible with the raw data files.

5. NIAID, NIH Grant Application R21 AI131451-01A1, A Novel Therapeutic Vaccine for HPV Oncogenesis, (b)(6); (b)(7)(C) Data in Figures 9-11 were falsified and/or fabricated by reporting immune response results that are incompatible with the raw data files.

6. NIAID, SBIR Phase II NIH Grant Application R44 AI126960-01, Novel Pan-Serovar Vaccine for Chlamydia, (b)(6); (b)(7)(C) : Data in Figure 9 were falsified and/or fabricated by reporting immune response results that are incompatible with the raw data files.

7. NIAID, SBIR Phase I NIH Grant Application R43 AI136224-01; A Novel Pan-Serovar Vaccine for Chlamydia, (b)(6); (b)(7)(C)): Data in Figure 3 were falsified and/or fabricated by reporting immune response results that are incompatible with the raw data files.

8. NIAID, NIH Grant Application R21 AI131013, A Novel Cellular Immune Zika Vaccine (b)(6); (b)(7)((b)(6); (b)(7)(C) Data in Figure 9 were falsified and/or fabricated by reporting immune response results that are incompatible with the raw data files.

9. NIAID, NIH Grant Application R01 AI126914, A Recombinant Human Vault CTL-Based HIV Vaccine Component, (b)(6); (b)(7)(C) Data in Figures 7 and 14 were falsified and/or fabricated by reporting immune response results that are incompatible with the raw data files.

10. NIAID, SBIR Phase I/II Fats-Track NIH Grant Application R44 AI128983, Design of a Novel CTL Retargeting Therapeutic HIV Vaccine, (b)(6); (b)(7)(C) Data in Figures 7 and 13 were falsified and/or fabricated by reporting immune response results that are incompatible with the raw data files.

11. NIAID, NIH Grant Application R21 AI142068-01, A Recombinant Human Vault CTL-Based HIV Vaccine Component (b)(6); (b)(7)(C) Data in Figures 8A, 8B, 8C, 9 and 10 were falsified and/or fabricated by reporting immune response results that are incompatible with the raw data files.

Please let me know if you need any additional information.

Best Regards,

(b)(6); (b)(7)(C)

Division of Investigative Oversight

Office of Research Integrity

1101 Wootton Parkway Suite 240

Rockville, MD 20852

Email: (b)(6); (b)(7)(C)

Desk: (240) 453-8800

From: (b)(6); (b)(7)(C) S/OASH)
To: H/OD) [E]
Cc: Runko, Alexander (HHS/OASH)
Subject: RE: ORI 2022-12
Date: Wednesday, August 10, 2022 3:16:58 PM
Attachments: (b)(6); (b)(7)(C)

Hi (b)(6); (b)(7)(C)

I realized that I didn't email you back regarding your follow-up question. Dr. Jiang appears to be at (b)(6); (b)(7)(C)

Regards,
(b)(6); (b)(7)(C)

From: (b)(6); (b)(7)(C)
Sent: Tuesday, August 2, 2022 2:47 PM
To: (b)(6); (b)(7)(C)
Cc: Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C)
Subject: RE: ORI 2022-12

Hi, (b)(6); (b)(7)(Thanks so much. This is very helpful.

One (hopefully last) follow-up question: do you know where Jiang is currently?

Thank-you!
(b)(6); (b)(7)(C)

From: (b)(6); (b)(7)(C)
Sent: Tuesday, August 2, 2022 2:44 PM
To: (b)(6); (b)(7)(C)
Cc: Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C)
Subject: RE: ORI 2022-12

Hi (b)(6); (b)(7)(C)

The grant (b)(6); (b)(7)(C)
(b)(6); (b)(7)(C)

Hope this helps.

Regards,

(b)(6); (b)(7)(C)

Division of Investigative Oversight
Office of Research Integrity
1101 Wootton Parkway Suite 240
Rockville, MD 20852

Email: (b)(6); (b)(7)(C)
Desk:

OASH | Office of Research Integrity

From: (b)(6); (b)(7)(C)
Sent: Tuesday, August 2, 2022 12:37 PM
To: Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C)
Subject: ORI 2022-12

Hi, Alex. In the Janina Jiang case, could you (or the assigned investigator) tell me which submission of UL1 TR000124 contains the fabricated/falsified Figure 6? I don't see an (b)(6); (b)(7)(C) tc after the grant number.

Thanks so much,

(b)(6); (b)(7)(C)

National Institutes of Health
6705 Rockledge Drive
Bethesda, MD 20817

From: (b)(6); (b)(7)(C) (HHS/OASH)
To: Runko, Alexander (HHS/OASH); (b)(6); HHS/OASH)
Subject: RE: Correction Notice for Jiang
Date: Tuesday, September 13, 2022 1:49:35 PM

Wanda got notification from Fed. Reg. that the correction notice will be published on Fri., 9/16.

(b)(6);
(b)(7)(C)

From (b)(6); (b)(7)(C) HHS/OASH)
Sent: Tuesday, September 13, 2022 10:20 AM
To: Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C) HS/OASH)
(b)(6); (b)(7)(C) hhs.gov>
Subject: Correction Notice for Jiang

Hi Alex and (b)(6);

Wanda signed and I submitted the correction notice to the *Fed. Reg*. this morning. My best guess is (b)(6); (b)(7)(C) Here's the link to where it'll be posted in case it's published while I'm away (b)(6); (b)(7)(C)

Thanks,

(b)(6); (b)(7)(C)

Division of Investigative Oversight

Office of Research Integrity

Ema (b)(6); (b)(7)(C)

Desk

<< OLE Object: Picture (Device Independent Bitmap) >>

From: Runko, Alexander (HHS/OASH)
To: Janina Jiang
Cc: (b)(6); (HHS/OASH)
Subject: RE: ORI 2022-12 revised VSA
Date: Tuesday, August 16, 2022 10:33:00 AM
Attachments: (b)(6); (b)(7)(C)

Dear Janina,

Thanks for your message (b)(6); (b)(7)(C)

ORI has sent a letter to the Research Integrity Officer (RIO) of your institution, (b)(6); (b)(7)(C) Vice President and Associate Dean for Research, on July 26, 2022. We notified (b)(6); (b)(7)(C) of the VSA, the supervision plan, (b)(6); (b)(7)(C) (b)(6); (b)(7)(C) If you are utilizing PHS (NIH) funds for your research, your institution would be required to have a supervision plan in place prior to you conducting any PHS-funded research (or if the research results would appear in a PHS grant/contract proposal). ORI can be available to speak with your RIO (b)(6); (b)(7)(C) or any other institutional official regarding your VSA and supervision plan of your research.

Bests,
Alex

Alexander Runko, Ph.D.
Director, Division of Investigative Oversight
Office of Research Integrity

Email: (b)(6); (b)(7)(C)
Office: (240) 453-8800
Desk: (b)(6); (b)(7)(C)
ori.hhs.gov/

OASH | Office of Research Integrity

From: Janina Jiang (b)(6); (b)(7)(C)
Sent: Monday, August 15, 2022 11:45 AM
To: Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C) hhs.gov>
Cc: (b)(6); (b)(7)(C) (HHS/OASH); (b)(6); (b)(7)(C) (HHS/OASH); (b)(6); (b)(7)(C) hhs.gov>; Jones, Wanda K. (DHHS/OS/OASH) (b)(6); (b)(7)(C) (b)(6); (b)(7)(C) s.gov>
Subject: Re: ORI 2022-12 revised VSA

Hi Dr. Runko,

(b)(6); (b)(7)(C)

(b)(6); (b)(7)(C) s, I signed the VSA at your request, (b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

(b)(6); (b)(7)(C) Also can you send the statement you made early on (see below) to them:

(b)(6); (b)(7)(C)

(b)(6); (b)(7)(C) Thank you so much!

Best,
Janina

On Thu, Jun 30, 2022 at 3:10 PM Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C) wrote:

> Dear Dr. Jiang,
>
> Thanks for speaking with us today, we heard your explanations and concerns, and appreciate the time that you have taken in cooperating to come to an agreement to settle this matter. As discussed, enclosed is the voluntary supervision agreement (VSA) with the revisions, and below are the statements from ORI that you can share with your supervisor. Please do not hesitate to contact us with additional questions, or if your supervisor would like to schedule a call with us.
>
> (b)(6); (b)(7)(C)

Best,
Alex

Alexander Runko, Ph.D.
Director, Division of Investigative Oversight
Office of Research Integrity

Email (b)(6); (b)(7)(C)
Office: (240) 453-8800
Desk: (b)(6); (b)(7)(C)
ori.hhs.gov/

OASH | Office of Research Integrity

From: (b)(6); (b)(7)(C) ASH)
To: Runko, Alexander (HHS/OASH)
Subject: Re: Letter from VCR Wakimoto
Date: Wednesday, August 17, 2022 3:53:57 PM
Attachments: (b)(6); (b)(7)(C)
(b)(to ORI August 2022.pdf

Hi Alex,

(b)(6); (b)(7)(C)

Thanks,
Regards,
(b)(6);
(b)(7)(C)

From: (b)(6); (b)(7)(C)
Sent: Wednesday, August 17, 2022 1:22 PM
To: (b)(6); (b)(7)(C)
Cc: Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C) @hhs.gov>; Pollack, Ann
(b)(6); (b)(7)(C)

Subject: Letter from VCR Wakimoto

Dear (b)(6); (b)(7)(C)

Hope this email finds you well. Attached please find a letter from Vice Chancellor Wakimoto. Should you have any questions or concerns, feel free to contact our office.

Sincerely,

Office of Research & Creative Activities
2248 Murphy Hall
Phone: (b)(6); (b)(7)(C)
UCLA

UCLA Research & Creative Activities

Roger M. Wakimoto, Ph.D.
2248 Murphy Hall
Mail Code: (b)(6);
Phone: (b)(6);
Email: (b)(6); (b)(7)(C)

August 16, 2022

VIA EMAIL

(b)(6); (b)(7)(C)
Division of Investigative Oversight
Office of Research Integrity
U.S. Department of Health and Human Services
Email: (b)(6); (b)(7)(C)

Re: DIO 7163

Dear (b)(6); (b)(7)(C)

I am writing to follow up your telephone conversations with Ann Pollack, Associate Vice Chancellor – Research, and to seek your help in making a factual correction to the record of the findings of research misconduct in DIO case 7163. As Associate Vice Chancellor Pollack advised when you spoke last week, the notice of findings of research misconduct against Janina Jiang, M.D., Ph.D., that appeared in the August 5, 2022 *Federal Register*, indicates that the first allegation involves a figure that was incorporated into a proposal that UCLA submitted to the National Institutes of Health (NIH) to support UCLA's Clinical and Translational Science Institute (CTSI). In actuality, that figure was incorporated into a proposal entitled (b)(6); (b)(7)(C) (b)(6); that was submitted to the (b)(6); (b)(7)(C) as part of an intramural granting program supported by funds from the CTSI award.

The proposal for (b)(6); (b)(7)(C) (b)(6); was *not* submitted to NIH. Figure (b) in the internal proposal was *not* incorporated into the (b)(6); (b)(7)(C) proposal that UCLA submitted to NIH.

I urge you and others at ORI to consider a factual correction of the August 5, 2022 *Federal Register* notice.

Sincerely,

(b)(6); (b)(7)(C)

Roger M. Wakimoto
Vice Chancellor for Research and Creative Activities
Research Integrity Officer

cc: DIO Director Alex Runko, Office of Research Integrity
Associate Vice Chancellor-Research Ann Pollack

From: Pollack, Ann
To: (b)(6); HHS/OASH)
Cc: Runko, Alexander (HHS/OASH); Wakimoto, Roger M
Subject: RE: Letter from VCR Wakimoto
Date: Friday, September 16, 2022 1:43:02 PM
Attachments: (b)(6); (b)(7)(C)

Dear (b)(6); (b)(7)(C

Thank you (and Alex) for taking such prompt action to correct the *Federal Register* notice. Vice Chancellor Roger Wakimoto and I very much appreciate it.

Ann

From: (b)(6); (b)(7)(C) @hhs.gov>
Sent: Friday, September 16, 2022 7:41 AM
To: Pollack, Ann (b)(6); (b)(7)(C)
Cc: Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C)
Subject: RE: Letter from VCR Wakimoto

Dear Ms. Pollack,

I am writing to inform that ORI issued a correction to remove National Institutes of Health (NIH) grant, UL1 TR000124, from the findings of research misconduct published earlier in the Federal Register. The correction can be found here (b)(6); (b)(7)(C)

Thank you.

Best Regards,

(b)(6); (b)(7)(C)

Division of Investigative Oversight
Office of Research Integrity
1101 Wootton Parkway Suite 240
Rockville, MD 20852

Email: (b)(6); (b)(7)(C)
Desk:

OASH | Office of Research Integrity

From: (b)(6); (b)(7)(C) (HHS/OASH)
Sent: Monday, September 12, 2022 11:27 AM
To: Pollack, Ann (b)(6); (b)(7)(C)
Cc: Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C)
Subject: RE: Letter from VCR Wakimoto

Dear Ms. Pollack,

Thank you for providing further clarification on the grant involvement. ORI will issue a correction in the Federal Register specific to this grant number, but it may take some time to go through the process. I will keep you updated. In the meantime if you have any questions or have any other information to share, please do not hesitate to contact me.

Best Regards,

(b)(6); (b)(7)(C)

Division of Investigative Oversight
Office of Research Integrity
1101 Wootton Parkway Suite 240
Rockville, MD 20852

Email (b)(6); (b)(7)(C)
Desk

OASH | Office of Research Integrity

From (b)(6); (b)(7)(C)
Sent: Friday, September 9, 2022 5:31 PM
To: (b)(6); (b)(7)(C)
Cc: Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C) >; Pollack, Ann (b)(6); (b)(7)(C)
Subject: Letter from VCR Wakimoto

Dear (b)(6); (b)(7)(C)

Hope this email finds you well. Enclosed please find a letter from VC Wakimoto. If you have any questions, feel free to reach out to Associate Vice Chancellor Ann Pollack.

Best regards,

(b)(6); (b)(7)(C)

UCLA Office of Research & Creative Activities

Email: (b)(6); (b)(7)(C)

Web: https://research.ucla.edu/

From: (b)(6); (b)(7)(C)
To: Runko, Alexander (HHS/OASH)
Subject: RE: DIO 2022-12 Jiang case
Date: Thursday, August 11, 2022 2:10:55 PM

Hi Alex,

Thanks. The issue she is raising is that the questioned figure was not in UL1TR000124 grant application submitted to NIH, (b)(6); (b)(7)(C)
(b)(6); (b)(7)(C)
(b)(6); (b)(7)(C) the respondent was responsible for the misconduct.

Regards,
(b)(6); (b)(7)(C)

From: Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C)
Sent: Thursday, August 11, 2022 1:54 PM
To: (b)(6); (b)(7)(C)
Subject: RE: DIO 2022-12 Jiang case

H (b)(6); (b)(7)(C)

Thanks for letting me know. I don't see a reason to change anything unless they provide some additional justification. (b)(6); (b)(7)(C)
(b)(6); (b)(7)(C)

-Alex

From: (b)(6); (b)(7)(C)
Sent: Thursday, August 11, 2022 1:16 PM
To: Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C)
Subject: DIO 2022-12 Jiang case

Hi Alex,

I spoke to Ann Pollack again and told her that at this point, UCLA may want to issue a clarification or statement on how the grant (UL1 TR000124) was involved. (b)(6); (b)(7)(C)
(b)(6); (b)(7)(C)
(b)(6); (b)(7)(C) Finally she wants to know if this can be corrected in federal register. She will discuss with the institution counsel and will write back to us.

I went back and looked at the report and this is how it is written (p.2). It clearly states the UCLA CTSI Grant# UL1TR000124.

(b)(6); (b)(7)(C) UCLA CTSI (b)(6); (b)(7)(C)
(b)(6); (b)(7)(C) (NCATS UCLA CTSI Grant # UL1TR000124; (b)(6);
(b)(6); (b)(7)(C)

They did provide a clarification, when I was not able to find the figure in grant. (b)(6); (b)(7)(C)
(b)(6); (b)(7)(C) the UL1 grant funds (b)(6); (b)(7)(C)

Thanks
(b)(6); (b)(7)(C)

From: (b)(6); (b)(7)(C) HHS/OASH)
To: Runko, Alexander (HHS/OASH)
Cc: (b)(6); (b)(7)(C))
Subject: RE: Correction Notice for Jiang
Date: Monday, September 12, 2022 2:29:52 PM
Attachments: Correction Notice FR Doc 2022-16867 Jiang 09-12-2022.docx

---

See if this works – I added the language below to II. and re-worded slightly (in track changes).

(b)(6);
(b)(7)(C)

From: Runko, Alexander (HHS/OASH (b)(6); (b)(7)(C)
Sent: Monday, September 12, 2022 2:17 PM
To: (b)(6); (b)(7)(C)
(b)(6); (b)(7)(C)
Subject: RE: Correction Notice for Jiang

Thanks (b)(6); I have one correction on page 2.

In terms of notice about the FRN correction on our website, would the following language suffice: "Due to additional information provided by the institution to ORI, it was determined that the NIH grant UL1 TR000124 did not fund or contain falsified/fabricated data and was removed from the research misconduct findings in the case."

From (b)(6); (b)(7)(C)
Sent: Monday, September 12, 2022 1:50 PM
To: Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C) S/OASH)
(b)(6); (b)(7)(C)
Subject: Correction Notice for Jiang

<< File: Correction Notice FR Doc 2022-16867 Jiang 09-12-2022.docx >> << File: FRN 2022-16867 Jiang 08-05-2022.pdf >>
Hi Alex (b)(6);

Attached is the correction notice for Jiang for your review. Also attached is the original FRN with highlighting of the text to be corrected (see 2nd page of the PDF).

Thanks,
(b)(6); (b)(7)(C)

Division of Investigative Oversight
Office of Research Integrity

Email: (b)(6); (b)(7)(C)
Desk:

<< OLE Object: Picture (Device Independent Bitmap) >>

COR14a

DRAFT [CORRECTION OF NOTICE]

REDACTED IN FULL AS A PRE-DECISIONAL RECORD

Withheld pursuant to exemption

(b)(5)

of the Freedom of Information Act

2022-16867 of August 5, 2022 (87 FR 48034-48036), make the following corrections:

1. On page 48035, first column, in FR Doc. 2022-16867, first paragraph, lines 9-12, remove "UL1 TR000124 submitted to the National Center for Advancing Translational Sciences (NCATS), NIH."
2. On page 48035, first column, in FR Doc. 2022-16867, seventh paragraph, lines 1-2, and second column, in FR Doc. 2022-16867, first paragraph, lines 1-3, remove "UL1 TR000124, 'UCLA Clinical and Translational Science Institute,' submitted to NCATS, NIH, Awarded Project Dates: June 1, 2011-August 31, 2016."
3. On page 48035, second column, in FR Doc. 2022-16867, thirteenth paragraph, line 1, remove "Figure 6 of UL1 TR0000124."

Dated: September 12, 2022

Wanda K. Jones, Dr.P.H.

Acting Director, Office of Research Integrity

Office of the Assistant Secretary for Health

BILLING CODE 4150-31-P

From: Runko, Alexander (HHS/OASH)
To: (b)(6); (b)(7)(C)
Subject: RE: Correction Notice for Jiang
Date: Monday, September 12, 2022 2:16:00 PM
Attachments: Correction Notice FR Doc 2022-16867 Jiang 09-12-2022.docx

---

Thanks (b)(5) I have one correction on page 2.

In terms of notice about the FRN correction on our website, would the following language suffice: "Due to additional information provided by the institution to ORI, it was determined that the NIH grant UL1 TR000124 did not fund or contain falsified/fabricated data and was removed from the research misconduct findings in the case."

From: (b)(5)
Sent: Monday, September 12, 2022 1:50 PM
To: Runko, Alexander (HHS/OASH) (b)(5)
(b)(5)
Subject: Correction Notice for Jiang

<< File: Correction Notice FR Doc 2022-16867 Jiang 09-12-2022.docx >> << File: FRN 2022-16867 Jiang 08-05-2022.pdf >>
Hi Alex (b)(5)

Attached is the correction notice for Jiang for your review. Also attached is the original FRN with highlighting of the text to be corrected (see 2nd page of the PDF).

Thanks,

(b)(5)
Division of Investigative Oversight
Office of Research Integrity

Email: (b)(5)
Desk: (

<< OLE Object: Picture (Device Independent Bitmap) >>

COR13a

DRAFT [CORRECTION OF NOTICE]

REDACTED IN FULL AS A PRE-DECISIONAL RECORD

Page 411 to Page 412

Withheld pursuant to exemption

(b)(5)

of the Freedom of Information Act

From: Runko, Alexander (HHS/OASH)
To: (b)(6); (b)(7)(C) HHS/OASH)
Cc: S/OASH)
Subject: RE: Correction notice for Jiang
Date: Monday, September 12, 2022 3:46:00 PM
Attachments: Correction Notice FR Doc 2022-16867 Jiang 09-12-2022 (002).docx

---

Good catch! I made one edit on page 2, #2.

From: (b)(6); (b)(7)(C) @hhs.gov>
Sent: Monday, September 12, 2022 3:29 PM
To: Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C)
Cc: (b)(6); (b)(7)(C) s.gov>
Subject: Correction notice for Jiang

<< File: Correction Notice FR Doc 2022-16867 Jiang 09-12-2022.docx >>
Hi Alex,

(b)(6); caught 2 more places in the FRN that need to be changed. See revisions in track changes in the attached doc.

Thanks,

(b)(6); (b)(7)(C)
Division of Investigative Oversight
Office of Research Integrity

Email (b)(6); (b)(7)(C)
Desk:

<< OLE Object: Picture (Device Independent Bitmap) >>

COR12a

DRAFT [CORRECTION OF NOTICE]

REDACTED IN FULL AS A PRE-DECISIONAL RECORD

Page 415 to Page 416

Withheld pursuant to exemption

(b)(5)

of the Freedom of Information Act

From: Runko, Alexander (HHS/OASH)
To: (b)(6); (b)(7)(C)
Cc:
Subject: RE: Correction Notice for Jiang
Date: Monday, September 12, 2022 2:39:00 PM

Ok, sounds like a plan.

(b)(6); – Once it is published, you can provide that notice and weblink to Wakimoto.

From: (b)(6); (b)(7)(C) s.gov>
Sent: Monday, September 12, 2022 2:35 PM
To: Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C)
Cc: (b)(6); (b)(7)(C)
Subject: RE: Correction Notice for Jiang

Thanks! I'll remove the track changes and send it to Wanda. She has to sign it, then I can submit. Once it's published, (b)(6); can link the FRN correction to the case summary on our website.

(b)(6);
(b)(7)(C)

From: Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C)
Sent: Monday, September 12, 2022 2:33 PM
To: (b)(6); (b)(7)(C)
Cc:
Subject: RE: Correction Notice for Jiang

Looks good! Wanda will want to see this before it goes out since I already had mentioned it to her.

From: (b)(6); (b)(7)(C)
Sent: Monday, September 12, 2022 2:30 PM
To: Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C)
Cc: (b)(6); (b)(7)(C)
Subject: RE: Correction Notice for Jiang

See if this works – I added the language below to II. and re-worded slightly (in track changes).

(b)(6);
(b)(7)(C)

From: Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C)
Sent: Monday, September 12, 2022 2:17 PM

To (b)(6); (b)(7)(C)
(b)(6); (b)(7)(C)
Subject: RE: Correction Notice for Jiang

Thanks (b)(6); , I have one correction on page 2.

In terms of notice about the FRN correction on our website, would the following language suffice: "Due to additional information provided by the institution to ORI, it was determined that the NIH grant UL1 TR000124 did not fund or contain falsified/fabricated data and was removed from the research misconduct findings in the case."

From: (b)(6); (b)(7)(C)
Sent: Monday, September 12, 2022 1:50 PM
To: Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C)
(b)(6); (b)(7)(C)
Subject: Correction Notice for Jiang

<< File: Correction Notice FR Doc 2022-16867 Jiang 09-12-2022.docx >> << File: FRN 2022-16867 Jiang 08-05-2022.pdf >>
Hi Alex (b)(6);

Attached is the correction notice for Jiang for your review. Also attached is the original FRN with highlighting of the text to be corrected (see 2nd page of the PDF).

Thanks,
(b)(6); (b)(7)(C)

Division of Investigative Oversight
Office of Research Integrity

Email (b)(6); (b)(7)(C)
Desk:

<< OLE Object: Picture (Device Independent Bitmap) >>

From: Runko, Alexander (HHS/OASH)
To: (b)(6); (b)(7)(C) HS/OASH)
Subject: RE: Correction Notice for Jiang
Date: Monday, September 12, 2022 2:16:00 PM
Attachments: Correction Notice FR Doc 2022-16867 Jiang 09-12-2022.docx

---

Thanks (b)(6); I have one correction on page 2.

In terms of notice about the FRN correction on our website, would the following language suffice: "Due to additional information provided by the institution to ORI, it was determined that the NIH grant UL1 TR000124 did not fund or contain falsified/fabricated data and was removed from the research misconduct findings in the case."

From: (b)(6); (b)(7)(C)
Sent: Monday, September 12, 2022 1:50 PM
To: Runko, Alexander (HHS/OASH) (b)(6); (b)(7)(C)
(b)(6); (b)(7)(C)
Subject: Correction Notice for Jiang

<< File: Correction Notice FR Doc 2022-16867 Jiang 09-12-2022.docx >> << File: FRN 2022-16867 Jiang 08-05-2022.pdf >>
Hi Alex (b)(6); (b)(7)(C)

Attached is the correction notice for Jiang for your review. Also attached is the original FRN with highlighting of the text to be corrected (see 2nd page of the PDF).

Thanks,

(b)(6); (b)(7)(C)
Division of Investigative Oversight
Office of Research Integrity

Email: (b)(6); (b)(7)(C)
Desk:

<< OLE Object: Picture (Device Independent Bitmap) >>

Page 420 to Page 421

Withheld pursuant to exemption

(b)(5)

of the Freedom of Information Act

From: (b)(6); (HHS/OASH)
To: Runko, Alexander (HHS/OASH); (b)(6); HHS/OASH)
Subject: Correction Notice for Jiang
Date: Monday, September 12, 2022 1:50:41 PM
Attachments: Correction Notice FR Doc 2022-16867 Jiang 09-12-2022.docx
FRN 2022-16867 Jiang 08-05-2022.pdf

Hi Alex (b)(6); (b)(7)(C)

Attached is the correction notice for Jiang for your review. Also attached is the original FRN with highlighting of the text to be corrected (see 2nd page of the PDF).

Thanks,

(b)(6); (b)(7)(C)

Division of Investigative Oversight

Office of Research Integrity

Email: (b)(6); (b)(7)(C)

Desk:

Page 423 to Page 424

Withheld pursuant to exemption

(b)(5)

of the Freedom of Information Act

adults in their transition from foster care to independent living in the areas of education, employment and earnings, housing and economic well-being, social support, well-being, health and safety, and criminal involvement. It focuses on helping young adults identify and achieve their goals while developing the skills necessary for independent living.

The evaluation is part of a larger project to help ACF build the evidence base in child welfare through rigorous evaluation of programs, practices, and policies. The activities and products from this project will contribute to evidence building in child welfare and help to determine the effectiveness of a program for youth formerly in foster care on young adult outcomes.

The implementation study will collect information through video conferences and site visits to the participating program and child welfare agency. Data collection activities for the implementation study began, as previously approved by OMB. Additional protocols are proposed as part of the implementation study. Proposed information collection activities include interviews and focus groups with administrators and staff from the program developer, child welfare agency, and program providers; online survey of program staff; interviews with youth who participated in the program; and focus groups with youth who participated in the program and who received services as usual.

Respondents: Program participants, young adults receiving services as usual, agency and program administrators and staff, other program stakeholders.

ANNUAL BURDEN ESTIMATES

Instrument	Respondents	Number of respondents (total over request period)	Number of responses per respondent (total over request period)	Average burden per response (in hours)	Total burden (in hours)	Annual burden (in hours)
Burden for previously approved, ongoing data collection						
Site Visit 2 Focus Group Guide for Staff.	LifeSet Specialists	12	1	1.5	18	9
LifeSet Team Supervisors						
Baseline Youth Survey	Youth Formerly in Foster Care.	470	1	0.6	282	141
Administrative data file	Agency and Program Staff	12	1	5	60	30
Burden for newly requested information collection						
Site Visit 3 Interview Guide for Administrators.	Child Welfare Agency Administrators. Licensed LifeSet Experts Provider Agency Administrators LifeSet Developer Administrators Provider Agency Administrators	22	1	1	22	11
Site Visit 3 Focus Group Guide for Staff.	LifeSet Specialists ..... LifeSet Team Supervisors Child Welfare Agency Caseworkers	28	1	1.5	42	21
LifeSet Specialist Survey	LifeSet Specialists	16	1	.3	5	3
Interview Guide for Youth ...	LifeSet Program Youth	12	1	1	12	6
Focus Group Guide for Youth.	LifeSet Program Youth ..... Services As Usual Youth	64	1	1.5	96	48

Estimated Total Annual Burden Hours: 269.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: 42 U.S.C. 677.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2022–16791 Filed 8–4–22; 8:45 am]

BILLING CODE 4184–25–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 Janina Jiang, M.D., Ph.D. (Respondent), former Assistant Researcher in the Department of Pathology & Laboratory Medicine at the David Geffen School of

Medicine, University of California, Los Angeles (UCLA). Respondent engaged in research misconduct in research included in grant applications submitted for U.S. Public Health Service (PHS) funds, specifically R43 CA228629–01 submitted to the National Cancer Institute (NCI), National Institutes of Health (NIH), UL1 TR000124 submitted to the National Center for Advancing Translational Sciences (NCATS), NIH, and P01 AI131294–01, R01 AI126914–01, R21 AI131013–01, R21 AI131451–01, R21 AI131451–01A1, R21 AI142068–01, R43 AI136224–01, R44 AI126960–01, and R44 AI128983–01 submitted to the National Institute of Allergy and Infectious Diseases (NIAID), NIH. The administrative actions, including supervision for a period of three (3) years, were implemented beginning on July 22, 2022, and are detailed below.

FOR FURTHER INFORMATION CONTACT: Wanda K. Jones, Dr.P.H., Acting 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:

Janina Jiang, M.D., Ph.D., University of California, Los Angeles: Based on the report of an investigation conducted by UCLA and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Janina Jiang, former Assistant Researcher in the Department of Pathology & Laboratory Medicine at the David Geffen School of Medicine, UCLA, engaged in research misconduct in research included in grant applications submitted for PHS funds, specifically R43 CA228629–01 submitted to NCI, NIH, UL1 TR000124 submitted to NCATS, NIH, and P01 AI131294–01, R01 AI126914–01, R21 AI131013–01, R21 AI131451–01, R21 AI131451–01A1, R21 AI142068–01, R43 AI136224–01, R44 AI126960–01, and R44 AI128983–01 submitted to NIAID, NIH.

ORI found that Respondent engaged in research misconduct by knowingly and recklessly falsifying and/or fabricating flow cytometry data that were included in the following eleven (11) grant applications submitted for PHS funds:

- R43 CA228629–01, "CTL Based Therapeutic Vaccine to Prevent or Interrupt HPV Mediated Oncogenesis," submitted to NCI, NIH, Awarded Project Dates: September 18, 2018-February 29, 2020.
- UL1 TR000124, "UCLA Clinical and Translational Science Institute," submitted to NCATS, NIH, Awarded Project Dates: June 1, 2011-August 31, 2016.
- P01 AI131294–01, "Defining Factors Controlling HIV Rebound," submitted to NIAID, NIH, Awarded Project Dates: August 10, 2017-July 31, 2022.
- R01 AI126914–01, "A Recombinant Human Vault CTL-Based HIV Vaccine Component," submitted to NIAID, NIH, on December 23, 2015.
- R21 AI131013–01, "A Novel Cellular Immune Zika Vaccine," submitted to NIAID, NIH, on June 14, 2016.
- R21 AI131451–01, "A Novel Therapeutic Vaccine for HPV Oncogenesis," submitted to NIAID, NIH, on June 14, 2016.
- R21 AI131451–01A1, "A Novel Therapeutic Vaccine for HPV Oncogenesis," submitted to NIAID, NIH, on June 13, 2017.
- R21 AI142068–01, "A Novel Therapeutic Vaccine for HPV Oncogenesis," submitted to NIAID, NIH, on February 12, 2018.
- R43 AI136224–01, "Development of A Novel Pan-Serovar Vaccine for Chlamydia," submitted to NIAID, NIH, on April 5, 2017.
- R44 AI126960–01, "Novel Pan-Serovar Vaccine for Chlamydia," submitted to NIAID, NIH, on January 4, 2016.
- R44 AI128983–01, "Design of a Novel CTL Retargeting Therapeutic HIV Vaccine," submitted to NIAID, NIH, on April 2, 2016.

ORI found that Respondent knowingly and recklessly falsified and/or fabricated flow cytometry data to represent interferon-γ (IFN-γ) expression in immune cells of mice administered with human recombinant vaults such that the represented data were incompatible with the raw experimental data. Specifically, Respondent falsified and/or fabricated flow cytometry data to represent:

- IFN-γ expression in the immune cells of mice injected subcutaneously or intranasally with human recombinant vaults containing HIV Gag peptides such that the vaccinated arm of the experiment showed antigen-specific T-cell responses in:

—Figure 6 of UL1 TR000124
—Figure 2 of R43 CA228629–01
—Figure 8 of R21 AI131451–01
—Figure 9 of R21 AI131451–01A1
—Figure 9 of R44 AI126960–01
—Figure 3 of R43 AI136224–01
—Figure 9 of R21 AI131013–01
—Figure 7 of R01 AI126914–01
—Figure 7 of R44 AI128983–01
—Figures 8A and 8B of R21 AI142068–01

- increased IFN-γ expression in the immune cells of mice injected with human recombinant vaults containing HPV peptides in Figure 3 of R43 CA228629–01
- dose-dependent increase in IFN-γ expression in the immune cells of mice injected with human recombinant vaults containing HIV Gag peptides in Figure 8 of P01 AI131294–01 and Figure 8C of R21 AI142068–01
- IFN-γ expression in the immune cells of mice administered intranasally with human recombinant vaults containing HPV peptides in Figure 10 of R21 AI131451–01A1 and Figure 10 of R21 AI142068–01
- IFN-γ expression in the immune cells of mice administered orally with human recombinant vaults containing HIV Gag peptides in Figure 11 of R21 AI131451–01A1 and Figure 9 of R21 AI142068–01
- IFN-γ expression in the immune cells of mice immunized subcutaneously with increasing doses of human recombinant vaults containing HIV Gag-1 spanning peptides in Figure 14 of R01 AI126914–01 and Figure 13 of R44 AI128983–01

Dr. Jiang entered into a Voluntary Settlement Agreement (Agreement) and voluntarily agreed to the following:

(1) Respondent will have her research supervised for a period of three (3) years beginning on July 22, 2022 (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 two 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 three (3) years from the effective date of this Agreement. The committee will review Respondent's primary data 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 Respondent's research. 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 Respondent's 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 2, 2022.

Wanda K. Jones,

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

[FR Doc. 2022–16867 Filed 8–4–22; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2022–0258]

National Maritime Security Advisory Committee; Vacancies

AGENCY: U.S. Coast Guard, Department of Homeland Security.

ACTION: Request for applications.

SUMMARY: The U.S. Coast Guard seeks applications to fill two member vacancies on the National Maritime Security Advisory Committee (Committee). This Committee provides advice and makes recommendations to the Secretary of Homeland Security, via the Commandant of the U.S. Coast Guard, on matters relating to national maritime security, including on enhancing the sharing of information related to cybersecurity risks that may cause a transportation security incident, between relevant Federal agencies and State, local, and tribal governments; relevant public safety and emergency response agencies; relevant law enforcement and security organizations; maritime industry; port owners and operators; and terminal owners and operators.

DATES: Your completed application should reach the U.S. Coast Guard on or before September 6, 2022.

ADDRESSES: Applications should include a cover letter expressing interest in an appointment to the National Maritime Security Advisory Committee and a resume detailing the applicant's relevant experience for the position applied for, with a brief biography. Incomplete applications will not be considered. Applications should be submitted via email with the subject line "Application for NMSAC" to *ryan.f.owens@uscg.mil.*

FOR FURTHER INFORMATION CONTACT: Mr. Ryan Owens, Alternate Designated Federal Officer of the National Maritime Security Advisory Committee; telephone: 202–372–1108 or email at *ryan.f.owens@uscg.mil*

SUPPLEMENTARY INFORMATION: The National Maritime Security Advisory Committee is a Federal advisory committee. The Committee was established on December 4, 2018, by § 602 of the *Frank LoBiondo Coast Guard Authorization Act of 2018,* Public Law 115–282, 132 Stat. 4192, and is codified in 46 U.S.C. 70112. The Committee operates under the provisions of the *Federal Advisory Committee Act,* (5 U.S.C. Appendix), and 46 U.S.C. 15109. The National Maritime Security Advisory Committee provides advice, consults with, and makes recommendations to the Secretary of Homeland Security, via the Commandant of the Coast Guard, on matters relating to national maritime security, including on enhancing the sharing of information related to cybersecurity risks that may cause a transportation security incident, between relevant Federal agencies and—

A. State, local, and tribal governments;

B. relevant public safety and emergency response agencies;

C. relevant law enforcement and security organizations;

D. maritime industry;

E. port owners and operators; and

F. terminal owners and operators.

The Committee is required to meet at least once a year in accordance with 46 U.S.C. 15109(a). We expect the Committee will hold meetings at least twice a year, but it may meet more frequently.

All members serve at their own expense and receive no salary or other compensation from the Federal Government. Members may be reimbursed for travel and per diem in accordance with Federal Travel regulations.

Under the provisions in 46 U.S.C. 15109(f)(6), if you are appointed as a member of the Committee, your membership term will expire on December 31 of the third full year after the effective date of your appointment. In this solicitation for Committee members, we will consider applications for two (2) positions:

- Facilities owners and operators.
- State and local governments.

Each member of the Committee must have particular expertise, knowledge, and experience in matters relating to the function of the Committee, which is to advise the Secretary of Homeland Security on the matters described above.

Consistent with 46 U.S.C. 15109(f)(4), Committee members are required to apply for, obtain, and maintain a government national security clearance at the Secret level. The U.S. Coast Guard will sponsor and assist candidates with this process.

In order for the Department, to fully leverage broad-ranging experience and education, the National Maritime Security Advisory Committee must be diverse with regard to professional and technical expertise. The Department is committed to pursuing opportunities, consistent with applicable law, to compose a committee that reflects the diversity of the nation's people.

If you are interested in applying to become a member of the Committee, email your cover letter and resume along with the brief biography to *ryan.f.owens@uscg.mil* via the transmittal method in the **ADDRESSES** section by the deadline in the **DATES** section of this notice.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Assistant Secretary for Health
Office of Research Integrity
1101 Wootton Parkway, Suite 240
Rockville, MD, 20852

Phone: 240-453-8200
FAX: 301-594-0043

July 26, 2022

Janina Jiang, M.D., Ph.D.
(b)(6); (b)(7)(C)

TRANSMITTED VIA EMAIL TO: (b)(6); (b)(7)(C)

RE: ORI 2022-12 (DIO 7163)

Dear Dr. Jiang:

On July 18, 2022, you agreed to a Voluntary Settlement Agreement (Agreement) in settlement of a finding of research misconduct made by the Office of Research Integrity (ORI). Based on the report of an investigation conducted by the University of California, Los Angeles (UCLA) and additional analysis conducted by ORI in its oversight review, ORI found that you engaged in research misconduct in research included in grant applications submitted for U.S. Public Health Service (PHS) funds, specifically R43 CA228629-01 submitted to the National Cancer Institute (NCI), National Institutes of Health (NIH), UL1 TR000124 submitted to the National Center for Advancing Translational Sciences (NCATS), NIH, and P01 AI131294-01, R01 AI126914-01, R21 AI131013-01, R21 AI131451-01, R21 AI131451-01A1, R21 AI142068-01, R43 AI136224-01, R44 AI126960-01, and R44 AI128983-01 submitted to the National Institute of Allergy and Infectious Diseases (NIAID), NIH.

The Agreement was signed by the Principal Deputy Assistant Secretary for Health and executed on July 22, 2022. Enclosed for your records is the executed Agreement.

Under the terms of the Agreement, the following administrative actions were implemented:

- You will have your research supervised for a period of three (3) years beginning on July 22, 2022 (the "Supervision Period"). Prior to the submission of an application for PHS support for a research project on which your participation is proposed and prior to your participation in any capacity in PHS-supported research, you will submit a plan for supervision of your duties to ORI for approval. The supervision plan must be designed to ensure the integrity of your research. You will not participate in any PHS-supported research until such a supervision plan is approved by ORI. You will comply with the agreed-upon supervision plan.

- The requirements for your supervision plan are as follows:

  - A committee of two senior faculty members at the institution who are familiar with your field of research, but not including your supervisor or collaborators, will provide oversight

and guidance for a period of three (3) years from the effective date of this Agreement. The committee will review your primary data on a quarterly basis and submit a report to ORI at six (6) month intervals setting forth the committee meeting dates and your compliance with appropriate research standards and confirming the integrity of your research.

- The committee will conduct an advance review of each application for PHS funds, or report, manuscript, or abstract involving your research. The review will include a discussion with you of the primary data represented in those documents and will include a certification to ORI that your data presented in the proposed application, report, manuscript, or abstract are supported by the research record.

- During the Supervision Period, you will ensure that any institution employing you submits, in conjunction with each application for PHS funds, or report, manuscript, or abstract involving PHS-supported research in which you are involved, a certification to ORI that the data provided by you 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.

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

- During the Supervision Period, you will exclude yourself 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.

In accordance with PHS policy, your name also has been entered in the PHS ALERT system. Your name will remain in the system for the Supervision Period, beginning on July 22, 2022, and ending on July 21, 2025.

Pursuant to ORI procedures, a brief summary of the misconduct finding and administrative actions will be placed in the *Federal Register*, the *NIH Guide for Grants and Contracts*, and the *ORI Newsletter* and on the ORI website.

Sincerely,

Wanda K. Jones, DrPH, MT(ASCP)

Digitally signed by Wanda K. Jones, DrPH, MT(ASCP)
Date: 2022.07.26 15:45:26 -04'00'

Wanda K. Jones, Dr.P.H.
Acting Director
Office of Research Integrity

Enclosure
Executed Voluntary Settlement Agreement

cc: Dr. Roger Wakimoto, Vice Chancellor for Research, UCLA
Dr. Tara A. Schwetz, ARILO, NIH
Dr. Michael Lauer, AERIO, NIH
(b)(6); (b)(7)(C)
Dr. Paulette Gray, RIO, NCI
(b)(6); (b)(7)(C)
Dr. Penny Burgoon, RIO, NCATS
Dr. Matthew Fenton, RIO, NIAID
Dr. Kenneth Santora, RIO, NIAID
(b)(6); (b)(7)(C)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Assistant Secretary for Health
Office of Research Integrity
1101 Wootton Parkway, Suite 240
Rockville, MD, 20852

Phone: 240-453-8200
FAX: 301-594-0043

July 26, 2022

Janina Jiang, M.D., Ph.D.
(b)(6); (b)(7)(C)

TRANSMITTED VIA EMAIL TO: (b)(6); (b)(7)(C)

RE: ORI 2022-12 (DIO 7163)

Dear Dr. Jiang:

On July 18, 2022, you agreed to a Voluntary Settlement Agreement (Agreement) in settlement of a finding of research misconduct made by the Office of Research Integrity (ORI). Based on the report of an investigation conducted by the University of California, Los Angeles (UCLA) and additional analysis conducted by ORI in its oversight review, ORI found that you engaged in research misconduct in research included in grant applications submitted for U.S. Public Health Service (PHS) funds, specifically R43 CA228629-01 submitted to the National Cancer Institute (NCI), National Institutes of Health (NIH), UL1 TR000124 submitted to the National Center for Advancing Translational Sciences (NCATS), NIH, and P01 AI131294-01, R01 AI126914-01, R21 AI131013-01, R21 AI131451-01, R21 AI131451-01A1, R21 AI142068-01, R43 AI136224-01, R44 AI126960-01, and R44 AI128983-01 submitted to the National Institute of Allergy and Infectious Diseases (NIAID), NIH.

The Agreement was signed by the Principal Deputy Assistant Secretary for Health and executed on July 22, 2022. Enclosed for your records is the executed Agreement.

Under the terms of the Agreement, the following administrative actions were implemented:

- You will have your research supervised for a period of three (3) years beginning on July 22, 2022 (the "Supervision Period"). Prior to the submission of an application for PHS support for a research project on which your participation is proposed and prior to your participation in any capacity in PHS-supported research, you will submit a plan for supervision of your duties to ORI for approval. The supervision plan must be designed to ensure the integrity of your research. You will not participate in any PHS-supported research until such a supervision plan is approved by ORI. You will comply with the agreed-upon supervision plan.

- The requirements for your supervision plan are as follows:

  - A committee of two senior faculty members at the institution who are familiar with your field of research, but not including your supervisor or collaborators, will provide oversight

and guidance for a period of three (3) years from the effective date of this Agreement. The committee will review your primary data on a quarterly basis and submit a report to ORI at six (6) month intervals setting forth the committee meeting dates and your compliance with appropriate research standards and confirming the integrity of your research.

- The committee will conduct an advance review of each application for PHS funds, or report, manuscript, or abstract involving your research. The review will include a discussion with you of the primary data represented in those documents and will include a certification to ORI that your data presented in the proposed application, report, manuscript, or abstract are supported by the research record.

- During the Supervision Period, you will ensure that any institution employing you submits, in conjunction with each application for PHS funds, or report, manuscript, or abstract involving PHS-supported research in which you are involved, a certification to ORI that the data provided by you 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.

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Sincerely,

Wanda K. Jones, DrPH, MT(ASCP)

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