



SRA INTERNATIONAL
ANNUAL MEETING
CHICAGO 2024
OCTOBER 26-30

The Dynamic Duo: Sponsored Programs and Compliance Offices Working Together!



Ella Trubman
Senior Director, Office of Sponsored Programs
and

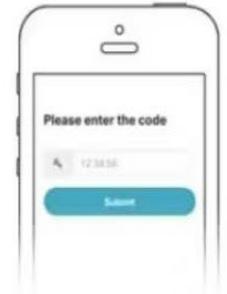
Monique Teixeira
Director of Compliance and Research Integrity Officer



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**WE ARE FUN
AND
INTERACTIVE**

AGENDA

- **Introductions**
- **What brought about the need for changes**
- **What changed for us internally**
- **Development of domestic and foreign affiliations tool**
- **Demonstrate use of tool: a case study**

What interoffice collaborations exist currently at your organizations?

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WHO WE ARE



Monique Teixeira
Compliance Director
Research Integrity Officer
Compliance and Legal Operations



Ella Trubman
Senior Director
Office of Sponsored Programs Pre-Award

WHAT DO WE DO

COMPLIANCE AND LEGAL OPERATIONS

- Conflict of Interest and Commitment
- Sub-Award Risk Analysis
- IRB Administration
- Research Security and Integrity
- Export Control

OFFICE OF SPONSORED PROGRAMS: PRE-AWARD

- Application Review and Submission
- Sub-recipient monitoring
- Sponsor Follow-up
- Facilitate institutional compliance

*How did we
get here??*

PRESS RELEASE

Ex-Harvard Professor China Ties Case



By [Gina Kolata](#)

Published April 26, 2023 Updated May 4, 2023

Share full article



Wednesday, September 1, 2021

Share



For Immediate Release

U.S. Attorney's Office, Western District of Michigan

The News

Charles Lieber, a former Harvard professor, was sentenced on Tuesday for national security concerns and for failing to disclose his ties to the Chinese government and for failing to disclose his ties to the Chinese government and for failing to be paid as part of a contract with a Chinese program, Thousand

Second Settlement With VARI Brings Total Settlement Proceeds To \$6.6 Million As NIH Imposes Specific Award Conditions On All VARI Grants

GRAND RAPIDS, MICHIGAN — The Department of Justice ("DOJ") announced today that Van Andel Research Institute ("VARI") has agreed to pay \$1 million to resolve allegations that implicated the Federal Claims Agency's failure to

Van Andel (December 2019)

- Violation of FCA due to submission of grant applications to the NIH that failed to disclose outside funding from the Chinese government.
- DOJ found that VARI failed, as an institute to take adequate steps to investigate the researcher's activities.
- Institute paid settlement for \$5.5 million, and the two subject researchers resigned.

Stanford University (October 2023)

- Agreed to pay \$1.9 million to resolve allegations under the FCA that investigators failed to disclose foreign research support in proposal submissions.
- Settlement relates to awards issued between 2015 - 2020 from the Dept of Army, Navy, Airforce, NASA, and NSF.
- Failure to disclose foreign support on current and pending.

Cleveland Clinic Foundation (May 2024)

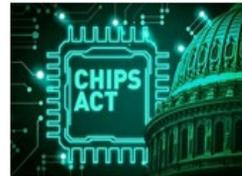
- Agreed to pay \$7.6M to resolve allegations that it violated the FCA by submitting grant applications and progress reports to NIH which failed to disclose that a key employee had pending and/or active financial research support from other sources.
- NIH implemented an award condition requiring a high-level CCF employee to personally attest to truth, completeness, and accuracy of all other grant support.

Introduction to Research Security

Research Security is protecting the means, know-how, and products of research until they are ready to be shared, by approval of the leader(s) of the research program and other stakeholders in their security.

[—JSR-22-08, JASON. 2023. " Research Program on Research Security](#)

Since 2019, the federal government has imposed a series of research security-based regulations. These regulations continue to evolve and will include new and expanded regulations.



So why is this big concept relevant to Research Administration?

And what does this really mean to us as Research Administrators?

WHO IS RESPONSIBLE FOR RESEARCH SECURITY AT YOUR ORGANIZATION?

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Research Administrators, who are the front line of providing disclosure documents, found themselves asking:



talents programs?

Challenges Faced at Scripps Research:

1. Who had what information?
2. How do we access that information?
3. Confidentiality
4. Consistent information from various funding sources
5. Unclear what information belonged on what disclosure
6. Accurate disclosures
7. Timely disclosures
8. “I have always done it this way”

WHAT OFFICE HOLDS THE MOST RELEVANT DISCLOSURES AT YOUR INSTITUTION?

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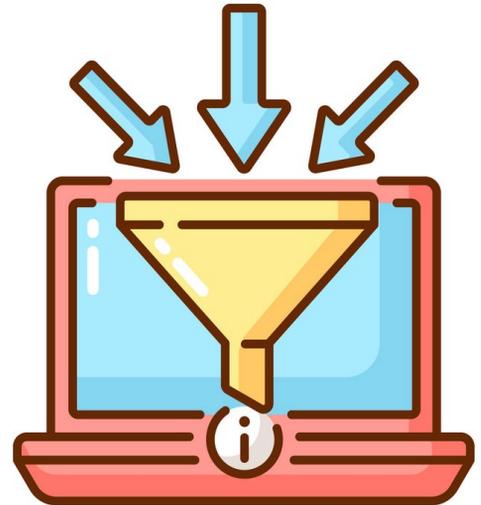
Do your institutions compare COI and COC disclosures with what Investigators submit on their Biosketch/Other Support Pages?

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SCRIPPS RESEARCH CASE STUDY

- Became clear Compliance and Legal Operations (CLO) was the best shepherd for all the information:
 - Keeper of COI and COC disclosures
 - Organized by 'External Entities'
- CLO Implemented International EPA (External Professional Activity) Reviews
- Added Specific Questions to COI/COC disclosures
- **CREATED EVERYONE'S FAVORITE TOOL...** an interactive Excel File



SCRIPPS RESEARCH CASE STUDY

Revised COI/COC questionnaire

1. Does your scope of work with the entity involve research or the design, conduct, or reporting of research? (Examples include, but are not limited to, work that may result in publication in an academic journal, designing a protocol, data analysis, performing any study related activities and/or procedures, gathering information, analyzing and evaluating evidence, drawing conclusions, advising on research, serving on a steering committee for a clinical trial, etc.)

■ YES = INVOLVES RESEARCH

2. Is this external entity providing you with any resources (regardless of monetary value) that are in support of and/or related to your research programs? (Resources include, but are not limited to, resources and/or financial support for yourself or lab personnel, provision of high-value materials that are not freely available, consulting agreements that include conducting research as part of the consulting activities, or in-kind contributions (e.g., office/laboratory space, equipment, supplies, etc.).

■ YES = CONSTITUTES OTHER SUPPORT

SCRIPPS RESEARCH CASE STUDY

International External Professional Activity (EPA) Reviews

CLO conducts routine reviews of personnel's International EPAs to verify compliance with related reporting requirements to their federal research sponsors and to Scripps Research.

International EPA Review Process Review:

- **Publications**
- **(EPA) disclosures and contracts**
- **Most recent Other Support and Biosketch pages**
- **List of federal grants**
- **MTA In Applications**
- **Travel Disclosures**
- **Open Search**

SCRIPPS RESEARCH CASE STUDY

Document is view only for grants/contract administrators



Identify Key Personnel

- Sheet sorted by personnel last name
- Domestic and Foreign Affiliations
- Each affiliation is its own line

SCRIPPS RESEARCH CASE STUDY

Reporter Name	Entity Name	Relationship Detail Name	County Code	Is this external entity providing you with any resources (regardless of monetary value) that are in support of and/or related to your research programs? (Resources include, but are not limited to, resources and/or financial support for yourself or lab personnel, provision of high-value materials that are not freely available, consulting agreements that include conducting research as part of the consulting activities, or in-kind contributions (e.g., office/laboratory space, equipment, supplied, etc.). If yes, this should be included on the Other Support Page. If blank =, reach out to CLO for future guidance.	Does your scope of work with the entity involve research or the design, conduct, or reporting of research? (Examples include, but are not limited to, work that may result in publication in an academic journal, designing a protocol, data analysis, performing any study related activities and/or procedures, gathering information, analyzing and evaluating evidence, drawing conclusions, advising on research, serving on a steering committee for a clinical trial, etc.)	CLO Notes
Faculty Member A	Big Science Corporation	Consultant	JPN	Y	Y	Required to be on BS and OS
Faculty Member A	Innovative Science Corporation	Founder	USA	N	N	Not required for BS or OS
Faculty Member B	Fancy New Therapeutics	SAB	USA	N	N	Required to be on BS, not requires on OS.
Faculty Member C	Drugs Inc.	Scientific Appointment (scientist, PI, visiting investigator)	USA	N	Y	Required to be on BS and if receives any support needs to be on OS
Faculty Member C	Pharma	Employee	GBR	N	N	Spouse Relationship, not required to be on OS or BS
Faculty Member C	Innovative Corporation	Editorial Board, Honoraria	USA			Not required for BS or OS
Faculty Member C	Innovative Corporation	Speaker	USA	N	N	Not required for BS or OS

SCRIPPS RESEARCH CASE STUDY

Sorted by
personnel last
name

Reporter Name	Entity Name	Relationship Detail Name	Country Code	Is this external entity providing you with any resources (regardless of monetary value) that are in support or and/or related to your research programs? (Resources include, but are not limited to, resources and/or financial support for yourself or lab personnel, provision of high-value materials that are not freely available, consulting agreements that include conducting research as part of the consulting activities, or in-kind contributions (e.g., office/laboratory space, equipment, supplied, etc.). If yes, this should be included on the Other Support Page. If blank =, reach out to CLO for future guidance.	Does your scope of work with the entity involve research or the design, conduct, or reporting of research? (Examples may result in publication in an academic journal, designing a protocol, data analysis, performing any study related activities and/or procedures, gathering information, analyzing and evaluating evidence, drawing conclusions, advising on research, serving on a steering committee for a clinical trial, etc.)	CLO Notes
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Faculty Member C	Innovative Corporation	Editorial Board, Honoraria	USA			Not required for BS or OS
Faculty Member C	Innovative Corporation	Speaker	USA	N	N	Not required for BS or OS

Each affiliation is its own line, even with same individual

SCRIPPS RESEARCH CASE STUDY

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Identify Key Personnel

- Sheet sorted by personnel last name
- Domestic and Foreign Affiliations
- Each affiliation is its own line

Navigate to affiliations and identify responses

- Y/N Questions
- CLO Notes
- Key

SCRIPPS RESEARCH CASE STUDY

Reporter Name	Entity Name	Relationship Detail Name	County Code	Is this external entity providing you with any resources (regardless of monetary value) that are in support of and/or related to your research programs? (Resources include, but are not limited to, resources and/or financial support for yourself or lab personnel, provision of high-value materials that are not freely available, consulting agreements that include conducting research as part of the consulting activities, or in-kind contributions [e.g., office/laboratory space, equipment, supplied, etc.]. If yes, this should be included on the Other Support Page. If blank =, reach out to CLO for future guidance.	Does your scope of work with the entity involve research or the design, conduct, or reporting of research? (Examples include, but are not limited to, work that may result in publication in an academic journal, designing a protocol, data analysis, performing any study related activities and/or procedures, gathering information, analyzing and evaluating evidence, drawing conclusions, advising on research, serving on a steering committee for a clinical trial, etc.)	CLO Notes
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Faculty Member C	Innovative Corporation	Speaker	USA	N	N	Not required for BS or OS

Reporters provide Yes/No answers

SCRIPPS RESEARCH CASE STUDY

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Faculty Member C	Innovative Corporation	Editorial Board, Honoraria	USA			Not required for BS or OS
Faculty Member C	Innovative Corporation	Speaker	USA	N		Not required for BS or OS

CLO provides notes based on Y/N answers and institutional policy

SCRIPPS RESEARCH CASE STUDY

POSITIONS OF EPAS IN STREAMLYNE (i.e. GAs will review in LIVE tab)	COI disclosure (form)	COI disclosure (Streamlyne)	Biosketch	Other Support
Board of Directors/Trustees	Yes	Yes	Yes	Unlikely
Consultant (Investigator is conducting research)	Yes	Yes	No	Yes
Consultant (Investigator is not conducting research)	Yes	Yes	No	No
Employee (Professor/Faculty)	Yes	Yes	Yes	Yes
Executive (CEO/CSO/ etc.)	Yes	Yes	Yes	Potential
Expert Witness	Yes	Yes	No	No
Founder/Co-founder	Yes	Yes	Yes	Potential
Other Foreign Affiliation (talent program, etc.)	Yes	Yes	Yes	Yes
Scientific Advisory Board (SAB)	Yes	Yes	Yes	No
Scientific Appointment (scientist, PI, visiting investigator)	Yes	Yes	Yes	Yes

SCRIPPS RESEARCH CASE STUDY

Document is view only for grants/contract administrators

During proposal review:



Identify Key Personnel

- Sheet sorted by personnel last name

Navigate to affiliations and identify responses

- Y/N Questions
- CLO Notes
- Key

Validate with Biosketch, Other Support, etc.

- Section B of Biosketch for Affiliations
- In Kind for Other Support

SCRIPPS RESEARCH CASE STUDY

Document is view only for grants/contract administrators

1

Identify Key Personnel

- Sheet sorted by personnel last name
- Domestic and Foreign Affiliations
- Each affiliation is its own line

2

Navigate to affiliations and identify responses

- Y/N Questions
- CLO Notes
- Key

3

Validate Biosketch and Other Support, etc. for Affiliations and Support

SCRIPPS RESEARCH CASE STUDY

B. Positions, Scientific Appointments, and Honors

Positions and Scientific Appointments

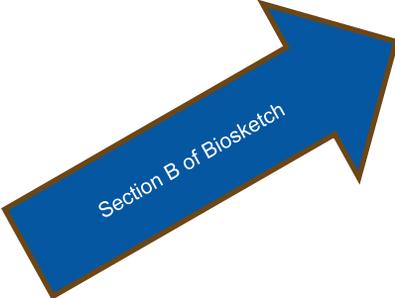
2021– Present	Associate Professor, Department of Psychology, Washington University, St. Louis, MO
2020 – Present	Adjunct Professor, McGill University Department of Psychology, Montreal, Quebec, Canada
2018 – Present	NIH Risk, Adult Substance Use Disorder Study Section, member
2015 – 2017	Consultant, Coastal Psychological Services, San Francisco, CA
2014 – 2021	Assistant Professor, Department of Psychology, Washington University, St. Louis, MO
2014 – 2015	NIH Peer Review Committee: Psychobiology of Aging, ad hoc reviewer
2014 – Present	Board of Advisors, Senior Services of Eastern Missouri
2013 – 2014	Lecturer, Department of Psychology, Middlebury College, Middlebury, VT
2011 – Present	Associate Editor, Psychology and Aging
2009 – Present	Member, American Geriatrics Society
2009 – Present	Member, Gerontological Society of America
2009 – 2013	Fellow, Intramural Research Program, National Institute on Drug Abuse, Baltimore, MD
2006 – Present	Member, American Psychological Association

Honors

2020	Award for Best in Interdisciplinary Ethnography, International Ethnographic Society
2019	Excellence in Teaching, Washington University, St. Louis, MO
2018	Outstanding Young Faculty Award, Washington University, St. Louis, MO

C. Contributions to Science

1. My early publications directly addressed the fact that substance use is often overlooked in older adults. However, because many older adults were raised during an era of increased drug and alcohol use, there are reasons to believe that this will become an increasing issue as the population ages. These publications found that older adults appear in a variety of primary care settings or seek mental health providers to deal with emerging concerns about a substance use disorder. These publications document this emerging concern and guide primary care providers and geriatric mental health providers to recognize symptoms, assess the nature of the behavior, and apply the necessary interventions. By providing evidence and simple clinical approaches, this body of work has changed the standards of care for older adults with substance use disorders and will continue to provide assistance in relevant medical settings well into the future. I served as the primary investigator or co-investigator in all of these studies.
 - a. Gryczynski, J., Shaft, B.M., Merrylye, R., & Hunt, M.C. (2013). Community based participatory research with late-life substance use disorder. *American Journal of Alcohol and Drug Abuse*, 15(3), 222-238.
 - b. Shaft, B.M., Hunt, M.C., Merrylye, R., & Venturi, R. (2014). Policy implications of genetic transmission of alcohol and drug use in women who do not use drugs. *International Journal of Drug Policy*, 30(5), 46-58.



Section B of Biosketch

SCRIPPS RESEARCH CASE STUDY



IN-KIND

*Summary of In-Kind Contribution: Post-doctoral fellow, Dr. John Smith, who conducts research activities in the Anderson lab. Salary supported by Oxford University.

*Status of Support: Active

*Primary Place of Performance: University of California, Los Angeles

Project/Proposal Start and End Date (MM/YYYY) (if available):

*Person Months (Calendar/Academic/Summer) per budget period: N/A

*Estimated Dollar Value of In-Kind Information: \$80,000

*Summary of In-Kind Contribution: Cell line XYZ provided by Dr. Jennifer Smith at Cornell University.

*Status of Support: Active

*Primary Place of Performance: University of California, Los Angeles

Project/Proposal Start and End Date (MM/YYYY) (if available):

*Person Months (Calendar/Academic/Summer) per budget period: N/A

*Estimated Dollar Value of In-Kind Information: estimate \$1,000

***Overlap** (summarized for each individual): None

I, PD/PI or other senior/key personnel, certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

*Signature: Anderson, R.R.

Date: March 25, 2021

TAKEAWAYS TO KEEP IN MIND





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Research Integrity Officer
Compliance and Legal Operations

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Senior Director
Office of Sponsored Programs Pre- Award