

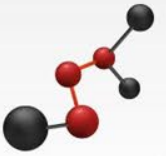
HCCA Research Compliance Conference

Unraveling Current U.S. and Foreign Legislation Affecting International Research

June 12, 2023

Xinning Shirley Liu, J.D., President, XL Law & Consulting P.A.
Kris West, J.D., M.S., Director, Research Ethics & Compliance, COGR

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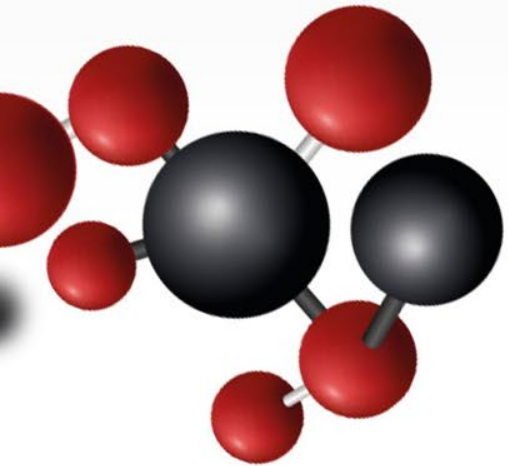
Strategies & Practical Advice

Tips and strategies for navigating thorny issues in domestic and international research

05

Q & A

An opportunity to take questions from the audience

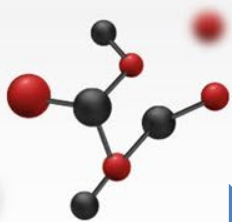


01

US RESEARCH LAWS

Impact of U.S. Research Security Laws on
International Collaborations





TIME OF REQUIREMENTS

Jan. 2021

- NSPM-33
- Requires research security programs for institution with >\$50M annual science & engineering

Jan. 2022

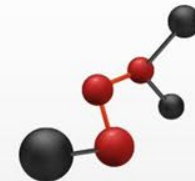
- NSPM-33 Implementation Guidance
- Identifies program elements: cybersecurity, foreign travel security, research security training, export control training
- Identifies cybersecurity elements

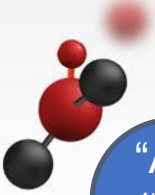
Aug. 2022

- CHIPS & Science Act of 2022
- Research security training requirements and certification
- Training guidelines and training modules

June 2023


- OSTP biosketch and research support disclosure forms – PROPOSED
- OSTP research security program standards -- PROPOSED





“As Federal departments and agencies (“agencies”) work to implement NSPM-33, it is critical that they do so in a consistent, coordinated manner that preserves the open and collaborative nature of the U.S. research enterprise, while providing strong and effective measures to protect research security and reinforce adherence to research responsibilities, transparency, and equity.”

**NSPM-33
Implementation
Guidance**



**But can international
collaborations still be
conducted with China?
Or is it too risky now. . .**

Investigators

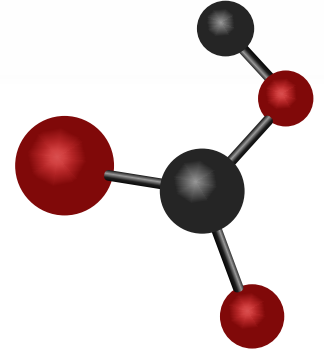




CONSIDERATIONS




- **Full Transparency**
 - Collaboration v. additional employment
 - Overlap – scientific, budgetary, commitment
 - Review processes
 - **Agreement Terms**
 - Who's reviewing?
 - Hallmarks of foreign talents programs
- 





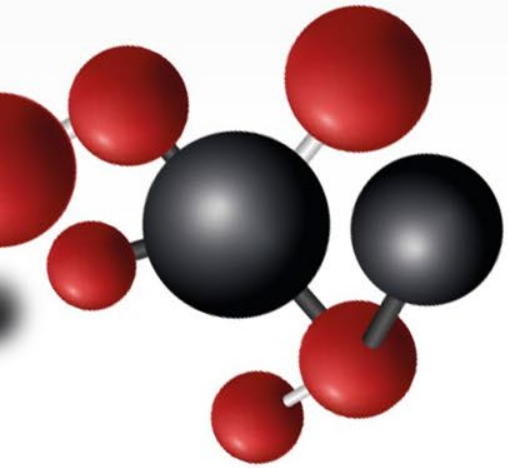
CONSIDERATIONS



- **Research type, circumstances, & subject matter**
 - Export controls
 - Intellectual property, proprietary information
 - Funders
 - **Reciprocity**
 - Can data be shared?
 - Can all funder and institutional obligations be met?
- 



**Of course, U.S. Laws are
not the only laws that
must be considered
when evaluating
collaborations . . .**



02

CHINESE RESEARCH LAWS

Impact of Chinese Laws on the Conduct of
Research in China





Research Proposal - Hypo

NIH Grant

Multi-Year Research

Clinical Site in China

Biological Samples

Joint Publication



Personal Information Protection Law

Effective November 1, 2021





China's Data Security & Privacy Regime



Cybersecurity Law (CSL)

Effective June 1, 2017

Data Security Law (DSL)

Effective September 1, 2021

Personal Information Protection Law (PIPL)

Effective November 1, 2021



GDPR vs PIPL

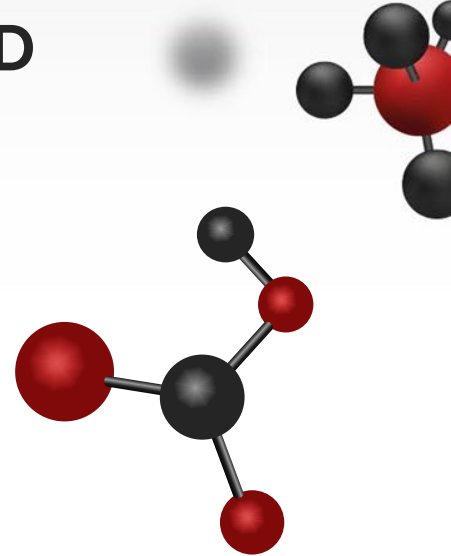
- Principles very similar
- Different framework
- Enforcement
- Public policy





PERSONAL INFORMATION DEFINED

- All kinds of information, recorded by electronic or other means, related to identified or identifiable natural persons, not including information after anonymization handling.
- **Anonymization** refers to the process of personal information undergoing handling to make it impossible to distinguish specific natural persons and impossible to restore





Anonymization
≠
De-identification



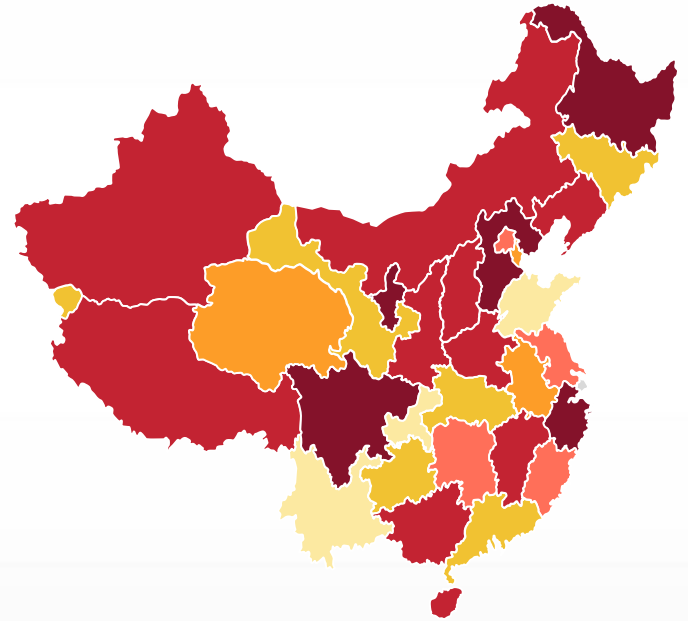
PIPL OVERVIEW

- Sensitive Personal Information
- Legal Basis
- Notice and Consent
- Effective Cross-Border Transfer Mechanism

JURISDICTIONAL SCOPE

- Domestic Scope

- Applies to the handling of all personal information of natural persons inside Mainland China



JURISDICTIONAL SCOPE

- **Extraterritorial Scope** – Applies to the PI handling outside China if they involve the PI of natural persons in China



ENFORCEMENT & PENALTIES

- Order correction
- Confiscation of unlawful income
- Suspension or termination of service
- Compensation to aggrieved individual
- Criminal liability





\$1.2 Billion USD
in Fines & Penalty

Personal fines
for President
and CEO



Foreign Trade Law

Effective December 30, 2022



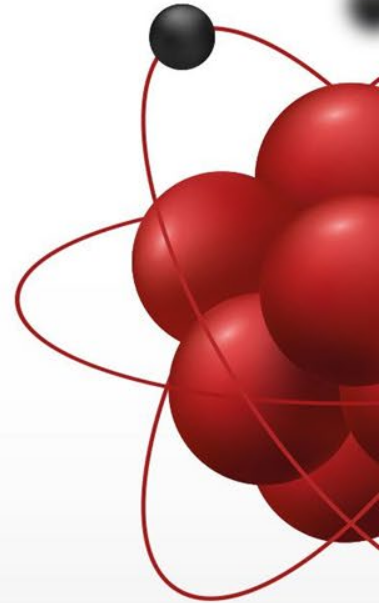


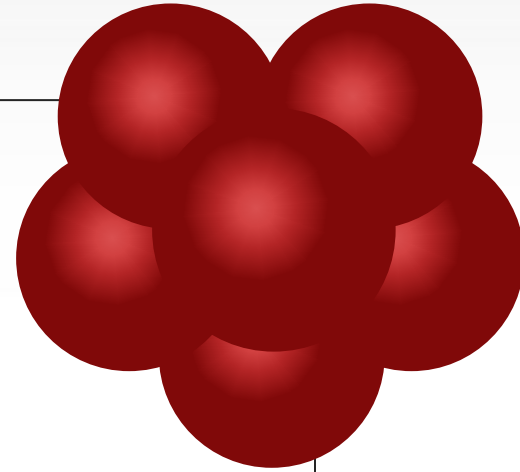
Regulates the **import and export of goods, technology**, and the international trade of **services**



Export Control Law

Effective December 1, 2020





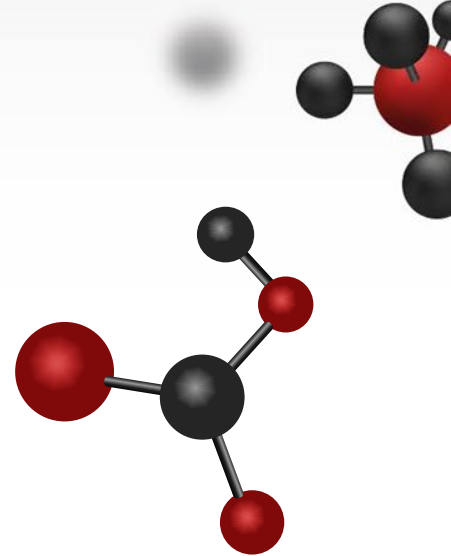
Regulates the export of

“dual-use items, military products,
nuclear, and *other items . . .*
related to maintaining the
national security and interest . . .”



PRC EXPORT CONTROL LAW

- Must apply for license from Ministry of Commerce prior to export
- NO EXCLUSION for Fundamental Research





Regulation on the Administration of Human Genetic Resources

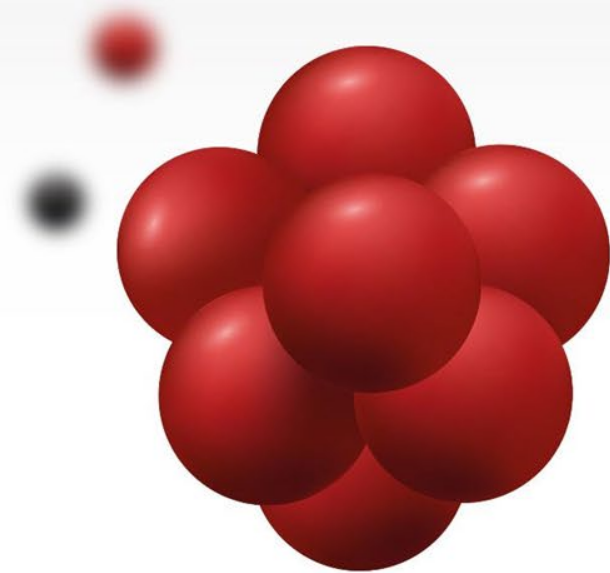
Effective July 1, 2019



”

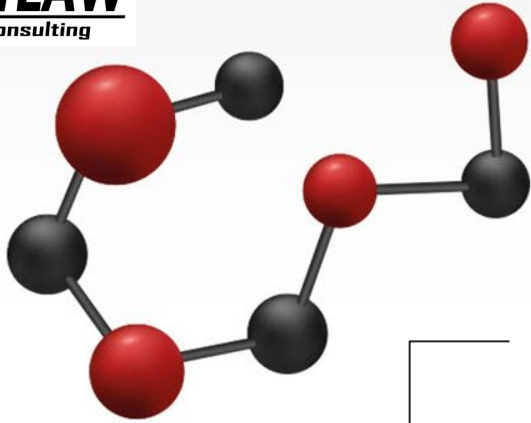
Applies to ”materials of human genetic resources” and “information on human genetic resources”

— PRC HGR Regulations



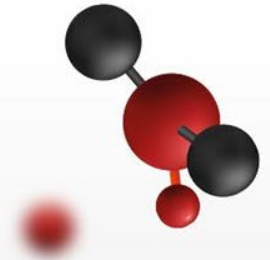
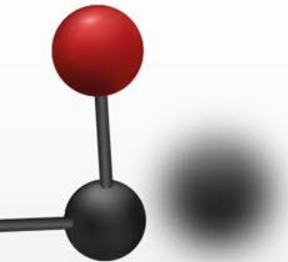
IMPACT ON U.S. ENTITIES

- Prohibition on HR prohibition and export
- Cooperation with Chinese partner
- Approval by Ministry of Science and Technology (MOST)



HRG Regulations Draft Rules

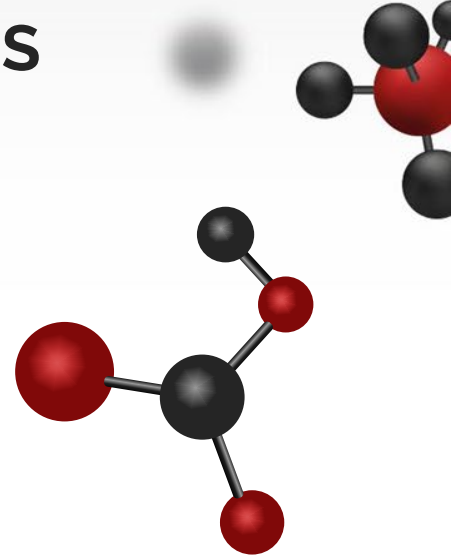
Issued by the MOST on March 14, 2022,
pursuant to the Biosecurity Law, Data
Security Law, and the HGR Regulations





HGR REGULATIONS – DRAFT RULES

- Market authorization on drugs and medical devices
- Clinical trials involving Chinese human genetic resources
- Security Review
- Enforcement and Penalties





Measures for the Management of Scientific Data

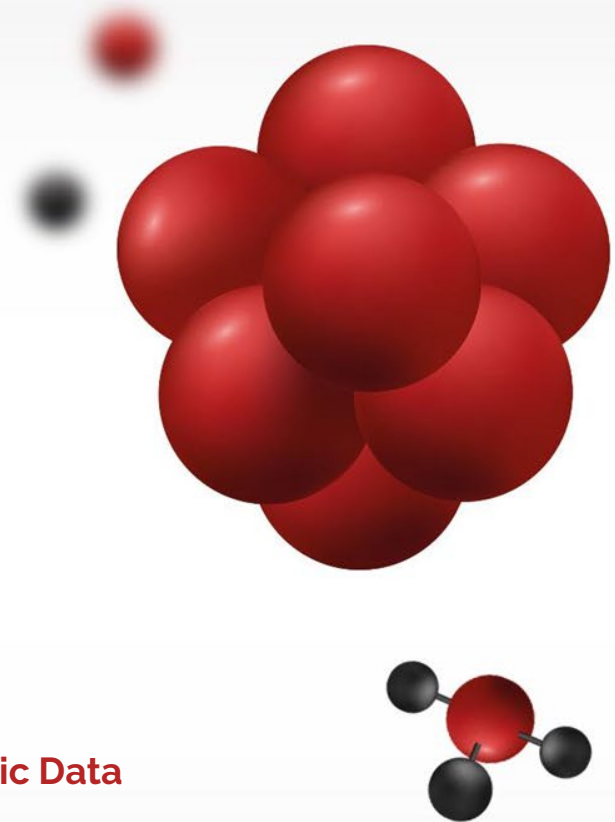
Effective May 17, 2018

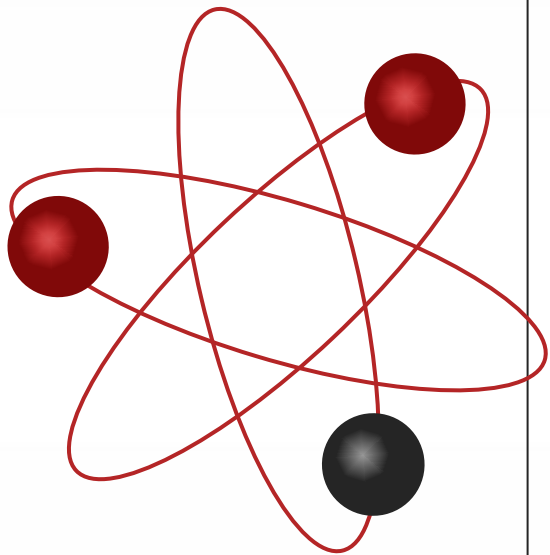


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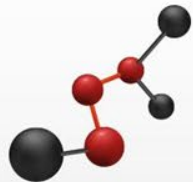
Scientific data = “the data generated through basic research, applied research, and experiment and development, among others, in natural science, engineering technology and science and other fields, and **the original data** obtained through observation and monitoring, investigation and survey, and inspection and testing and other methods used for scientific research activities and the derived data thereof”

— PRC Measures on the Management of Scientific Data





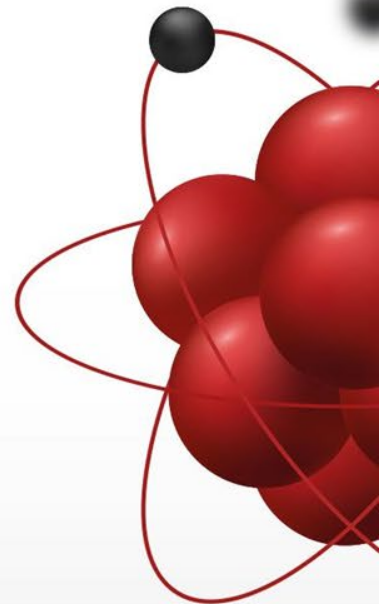
For PRC government-funded projects, **Chinese authors must submit scientific data to their employers *before*** the publication of papers in foreign (U.S. or other non-PRC) academic journals.





Anti- Espionage Law

Amendments Effective July 1, 2023



Expanded definition of “espionage activities”

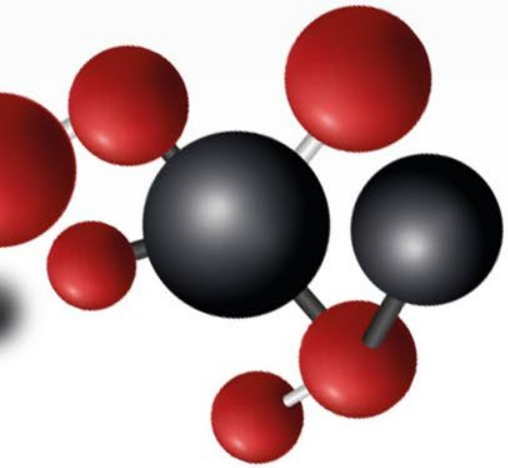
“Stealing, spying, purchasing, or illegally providing any state secret or intelligence, and other documents, data, materials, and items *relating to the national security and interest* or causing a state employee to betray his or her country by instigation, inducement, threat, or bribery, **which is committed by an overseas institution, organization, or individual** other than an espionage organization and its agent **or by any other person as instigated or funded by the aforesaid** or committed by a domestic institution, organization, or individual in collusion with the aforesaid”



CHINESE ANTI-FOREIGN ESPIONAGE LAW

- Investigative Authority
- Penalties
- Implications for U.S. entities





03

Foreign Research Checklist

Key issues to review in any international
research collaboration

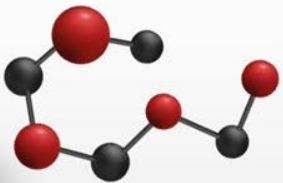


Top Five Foreign Collaborators for the United States



1. China
2. United Kingdom
3. Germany
4. Canada
5. France

Measured by the number
of scientific publications





FOREIGN RESEARCH CHECKLIST

01

Due Diligence

What due diligence do I need to conduct on entities with which I might partner?

Type of Commodity

What goods or technologies do I need to import/export?

02

Type of Sector

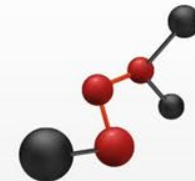
What are the regulatory compliance requirements governing the specific research sector?

03

Type of Research

What are the regulatory compliance requirements governing the type of research or the type of collaboration?

04



FOREIGN RESEARCH CHECKLIST



05

Type of Data

Does the research collaboration involve data that would constitute personal information and/or sensitive personal information?

Registrations and Approvals

What registrations and/or approvals is needed to conduct this research?

06

IP and Publication Rights

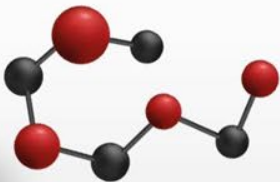
What protections does the researchers need to protect their intellectual property and publication rights?

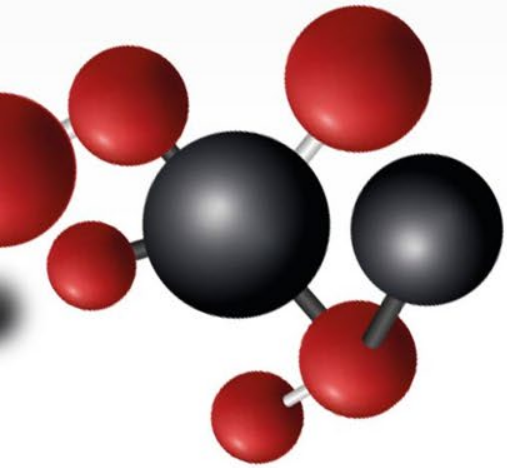
07

Education and Training

What training do the U.S. researchers/other participants need in order to ensure compliance with foreign laws and regulations?

08





04

Strategies & Practical Advice

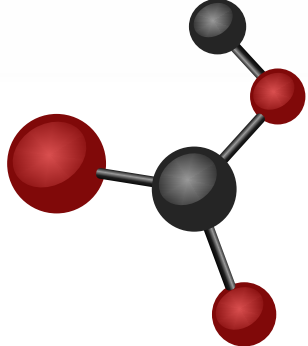
Tips and strategies for navigating thorny issues
in domestic and international research





CONFLICTS OF INTERESTS & COMMITMENT



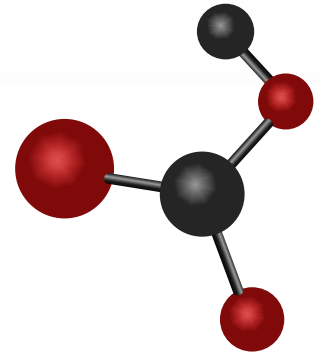
- GAO Report – [Federal Research: Agency Actions Needed to Address Foreign Influence](#)
 - Conflicts of commitment as “non-financial” conflicts of interest
 - Researcher personal financial COI & COC
 - Bias research v. capacity to conduct research
 - How is commitment being tracked?
- 



CONFLICTS OF INTERESTS & COMMITMENT



- New regulations on the way:
 - [NASA](#)
 - [Department of Energy](#)
- Resources
 - [Principles for Evaluating Conflict of Commitment Concerns in Academic Research](#) (9/22)
 - [Analyzing Personal Financial and Institutional Conflicts of Interest in Academic Research Contexts](#) (3/23)



Berkeley's \$220M Mistake Exposed in Massive Deal With China

OOOPS!

J.C. Berkeley repeatedly neglected to disclose its deal with China to the U.S. government.



Yuichiro Kakutani

Updated May. 26, 2023 2:12PM ET / Published May. 22, 2023 4:59AM ET



EXCLUSIVE

"The MIT of China"



Institution Transparency & COI Concerns

- Procurement
- Intellectual Property
- Funding
- Disclosure requirements
 - Department of Education
 - NEW-NSF



MONITORING RESEARCH PERFORMANCE – INTERNATIONAL SUBAWARDEES

U.S. Department of Health and Human Services
Office of Inspector General

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Copies can also be obtained by contacting the Office of Public Affairs at Public.Affairs@oig.hhs.gov.

The National Institutes of Health and EcoHealth Alliance Did Not Effectively Monitor Awards and Subawards, Resulting in Missed Opportunities to Oversee Research and Other Deficiencies

01-25-2023 | A-05-21-00025 | [Complete Report](#) | [Report in Brief](#)

Why OIG Did This Audit

OIG initiated this audit because of concerns regarding the National Institutes of Health's (NIH's) grant awards to EcoHealth Alliance (EcoHealth), NIH's monitoring of EcoHealth, and EcoHealth's use of grant funds, including its monitoring of subawards to a foreign entity.

Our objectives were to determine whether: (1) NIH monitored grants to EcoHealth in accordance with Federal requirements and (2) EcoHealth used and managed its NIH grant funds in accordance with Federal requirements.

What OIG Recommends, and National Institutes of Health's and EcoHealth's Comments

We recommend that NIH ensure that EcoHealth accurately and in a timely manner report award and subaward information; ensure that administrative actions are appropriately performed; **implement enhanced monitoring, documentation, and reporting requirements for recipients with foreign subrecipients; . . .**




NEW NIH REQUIREMENTS



- [NIH Updated Policy Guidance for Subaward/Consortium Written Agreements](#)

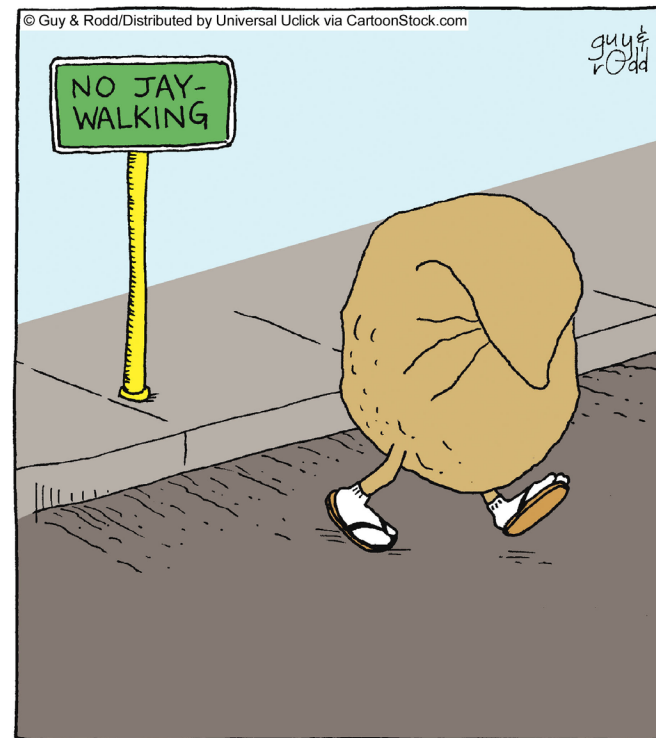
Notice Number: NOT-OD-23-133 **Effective Date:** Oct. 1, 2023

- The recipient must enter into a formal written agreement, **signed, and agreed to by both parties**, with each consortium participant/**subrecipient** that addresses the negotiated arrangements for meeting the scientific, administrative, financial, and reporting requirements of the grant, including those necessary to ensure compliance with all applicable Federal regulations and policies and facilitate an efficient collaborative venture. *If a subrecipient is unwilling to accept the requirements outlined in this section, by signing a written agreement, then an agreement cannot be issued.*
 - “For foreign subrecipients, a provision requiring the foreign subrecipient to provide copies of all lab notebooks, all data, and all documentation that supports the research outcomes as described in the progress report. These supporting materials must be provided to prime recipient with each scientific update (no less than once every three months) in line with the timelines outlined in the agreement.”
- 



FINAL TAKEAWAYS

- Identify regulatory compliance requirements
- Beware of data privacy implications
- Don't skip the due diligence
- No shortcuts to internal training and communications
- Hire local counsel with relevant experience



WON - TON DISREGARD FOR THE LAW



Q & A



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- Kris West
Council on Government Relations
kwest@cogr.edu

