

UC San Diego

RESEARCH COMPLIANCE AND INTEGRITY

UC San Diego

RESEARCH COMPLIANCE AND INTEGRITY

- Conflict of Interest (COI)
- Dual Use Research of Concern (DURC)
- Export Control and Facility Security
- Institutional Animal Care and Use Committee (IACUC)
- Research Ethics and Integrity (Research Misconduct)
- ClinicalTrials.Gov Compliance

Website: RCI.UCSD.EDU

Helpline: (858) 822-4939

Email: rci@ucsd.edu

UC San Diego

RESEARCH COMPLIANCE AND INTEGRITY

Export Control Office

Brittany Whiting

Director

EXPORT CONTROL OFFICE

- Identifies and manages export risks for U.S. national security & foreign policy to facilitate university research
 - Export Controls
 - Dual Use Research of Concern (DURC)
 - Facility Security
- Advises on and obtains export licenses for:
 - International payments, shipments, travel and collaborations
 - Sanctioned country activities with Cuba, Iran, North Korea, Syria & Sudan
 - Restricted parties
- Develops technology control plans with researchers for export restricted items



WHAT IS AN “EXPORT”?

- Physical Export: sending any material to foreign location (includes hand carry & electronic exports)
- Deemed Export: disclosing “controlled” technical data either written, oral, or visually in the United States to a foreign person



WHY IT MATTERS



Delays – Can impact research timeline

- Factor that can extend award negotiation time – may involve institutional decisions
- Factor to be considered if/when accepting another parties information
- Likely to require additional internal review processes
- Time & resources – can effect project schedules – even after the award

PI's and administrators need to be involved

- Fines – loss of research dollars or export privileges:
- False export declarations EEI \$10,000 per violation
- Failure to obtain an export license: BIS \$284,000 or twice the shipment value, ITAR \$1,094,010 per violation, denial of export privileges, and 10 years prison
- Jail time

Debarment & loss of export privileges

EXPORT CONTROL IS A TEAM EFFORT



SYSTEMS FOR EXPORT REVIEWS

People

- Foreign Visiting Scholars & Grads
- Foreigner access to export restricted technology

Places

- Foreign shipments
- Foreign payments
- Sanctioned countries transactions
- Travel pre-authorization alerts

Things

- Procurement- Purchasing
- Contracts and Grants systems
- Biohazard Use Authorizations
- Chemical Hazard Use Authorizations

PLACES: SANCTIONED COUNTRIES



- OFAC Comprehensive Sanctions for imports, exports, financial transactions and services for:
 - Cuba, Iran, North Korea, Syria and Sudan
- Other countries with non-comprehensive sanctions include: Belarus, Burundi, Central African Republic, Iraq, Lebanon, Libya, Somalia, South Sudan, Russia/Ukraine, Venezuela, Yemen, Zimbabwe

This list is not exhaustive

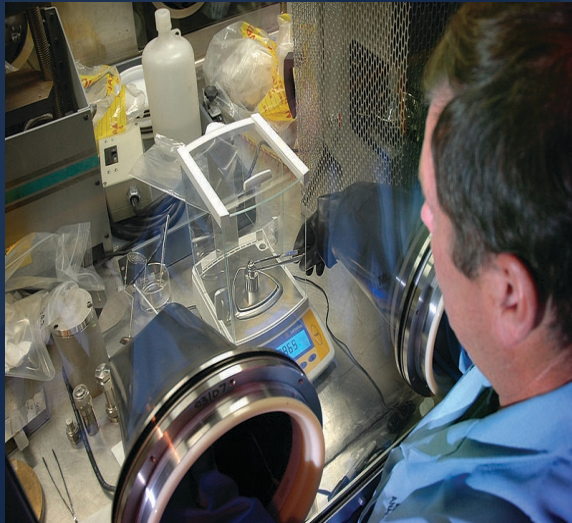
PEOPLE: RESTRICTED OR PROHIBITED PERSON OR ENTITY?

- The US Government issues various lists of individuals & entities both in the U.S. & abroad that have committed export violations or other serious offenses.
 - Terms & conditions require no debarred, disqualified or ineligible persons
 - Part of funding awards, procurement and service agreements
- Financial dealings or export transactions with Restricted or Prohibited parties is prohibited.
 - Terrorists
 - Weapons Proliferators
 - Export Violators
 - Drug Traffickers
- Visual Compliance Screening Tool

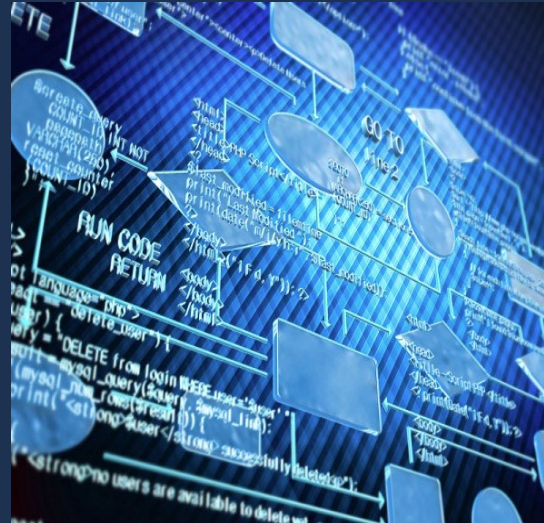


THINGS: WHAT IS EXPORT RESTRICTED?

Equipment &
Materials



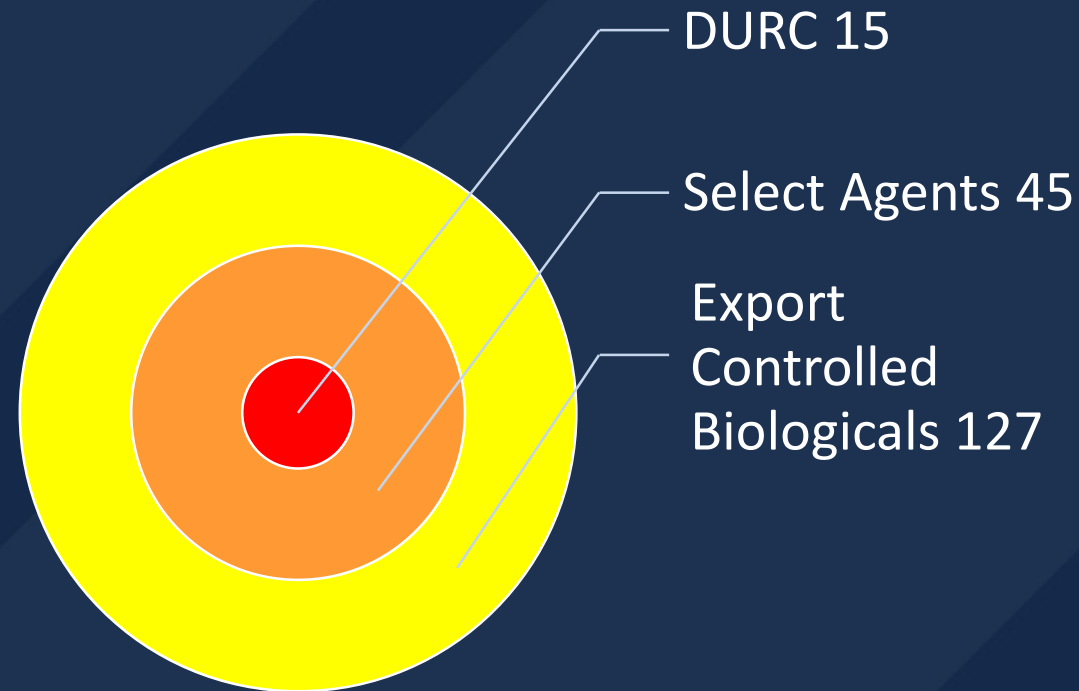
Software



Technology or
Technical Data



U.S. REGULATORY CONTROLS OF BIOLOGICALS & TOXINS



- Export Restricted Biologicals require export licensing for shipment to any country.
- Please contact export@ucsd.edu for all international shipments to determine export paperwork requirements.

**CONTACT EXPORT CONTROL
FOR INTERNATIONAL SHIPMENT REVIEWS**

export@ucsd.edu or 858-246-3300

EXPORT CONTROL OFFICE CONTACT INFORMATION

Export Control Office Website:

[http://blink.ucsd.edu/sponsor/
exportcontrol/](http://blink.ucsd.edu/sponsor/exportcontrol/)

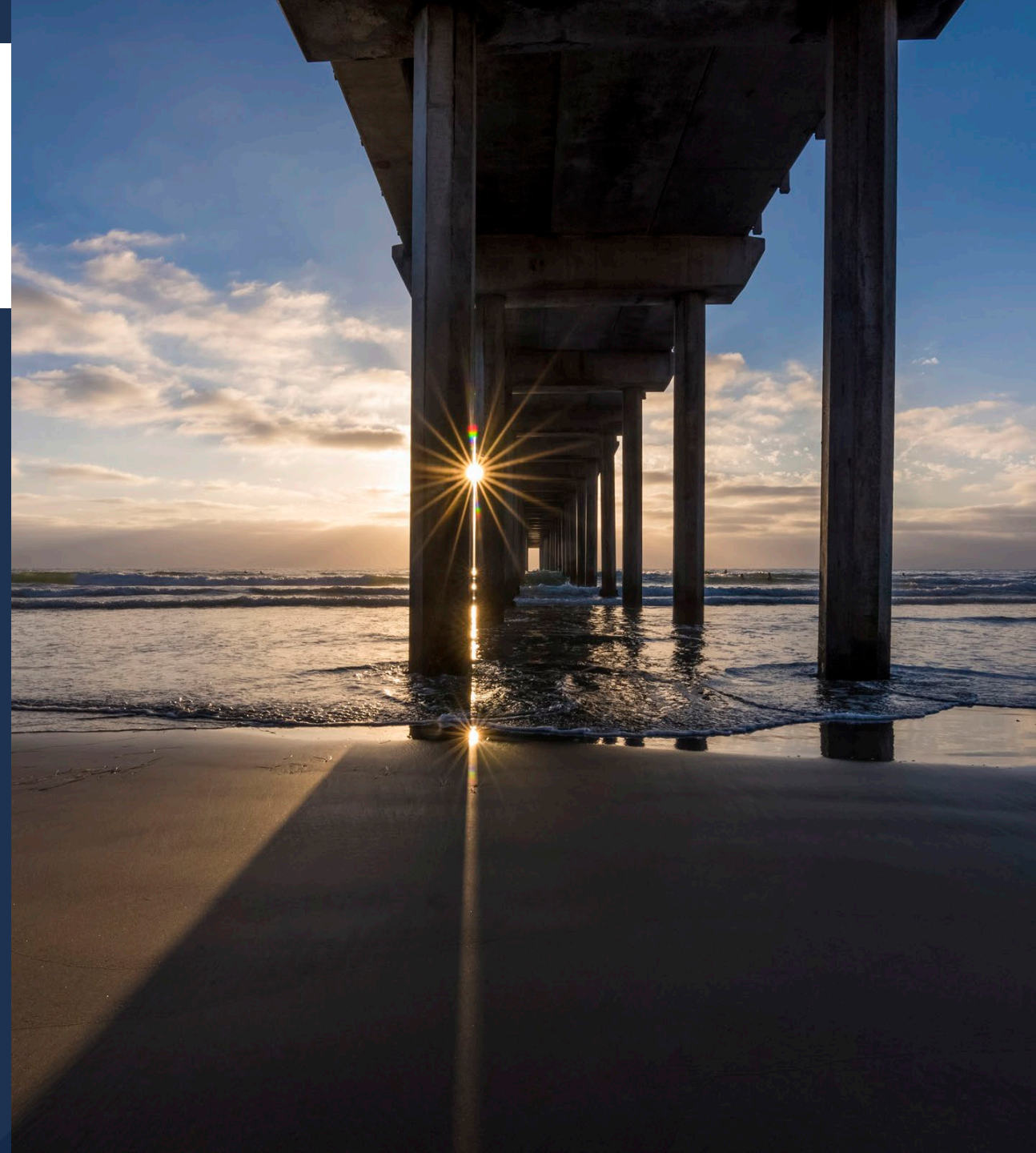
Email: export@ucsd.edu

Telephone: 858-246-3300

Brittany Whiting, Director

Garrett Eaton, Sr. Export Analyst

Ryan Jordan, Export Analyst



FOREIGN INFLUENCE

GOVERNMENT CONCERN OVER UNIVERSITIES & FOREIGN INFLUENCE

- Public cases of Export Violations involving Universities
- Increased scrutiny by Congress, White House, and Federal Agencies
- Increased visits by federal agencies to Universities, FBI, BIS, ICE
- Economic espionage concerns



EXPORT VIOLATION INVOLVING UNIVERSITY PROFESSOR 2009

SHARON WEINBERGER SECURITY 09.17.09 09:00 AM

FROM IVORY TOWER TO IRON BARS: SCIENTISTS RISK JAIL TIME FOR VIOLATING EXPORT LAWS



John Reece Roth never thought he'd be going to prison for his research on plasma physics. But that's precisely where the 72-year old University of Tennessee professor will likely spend the next four years.

Roth was sentenced last month for sharing his research with foreign graduate students and taking a laptop with his research to China. Along with his university research, he was working on an unclassified contract from the U.S. Force looking at ways to reduce drag on drones using plasma actuators.

The case has been closely watched by university professors

<https://www.wired.com/2009/09/from-ivory-tower-to-iron-bars-academics-risk-jail-time-for-violating-export-laws/>

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TWEET



COMMENT



EMAIL

JUNE 22, 2018 \$1B EXPORT CONTROL FINE TO ZTE CHINA

Largest Export Control
Fine Ever Issued

CNN MoneyCompaniesMarketsTechMedia

U.S. 🔍 ☰


ZTE pays \$1 billion fine to US over sanctions violations

by Donna Borak @donnaborak
🕒 June 22, 2018: 4:01 PM ET


Recommend 69

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Social Surge - What's Trending




Airbus: Brexit chaos threatens our future in UK



Report: Prosecutors subpoena National Enquirer records in Michael Cohen investigation



Rachel Maddow breaks down in tears while discussing border crisis



Wilbur Ross: ZTE deal a 'strong deterrent'


Wilbur Ross: ZTE deal a 'strong deterrent'

China's ZTE, which the US government has accused of repeated sanctions violations, has paid a \$1 billion fine, a US Commerce Department official said Friday.


The payment comes days after President Donald Trump tried to persuade two dozen lawmakers — mostly Republicans — that the fine and the assignment of an American monitoring team would be sufficient punishment for ZTE.

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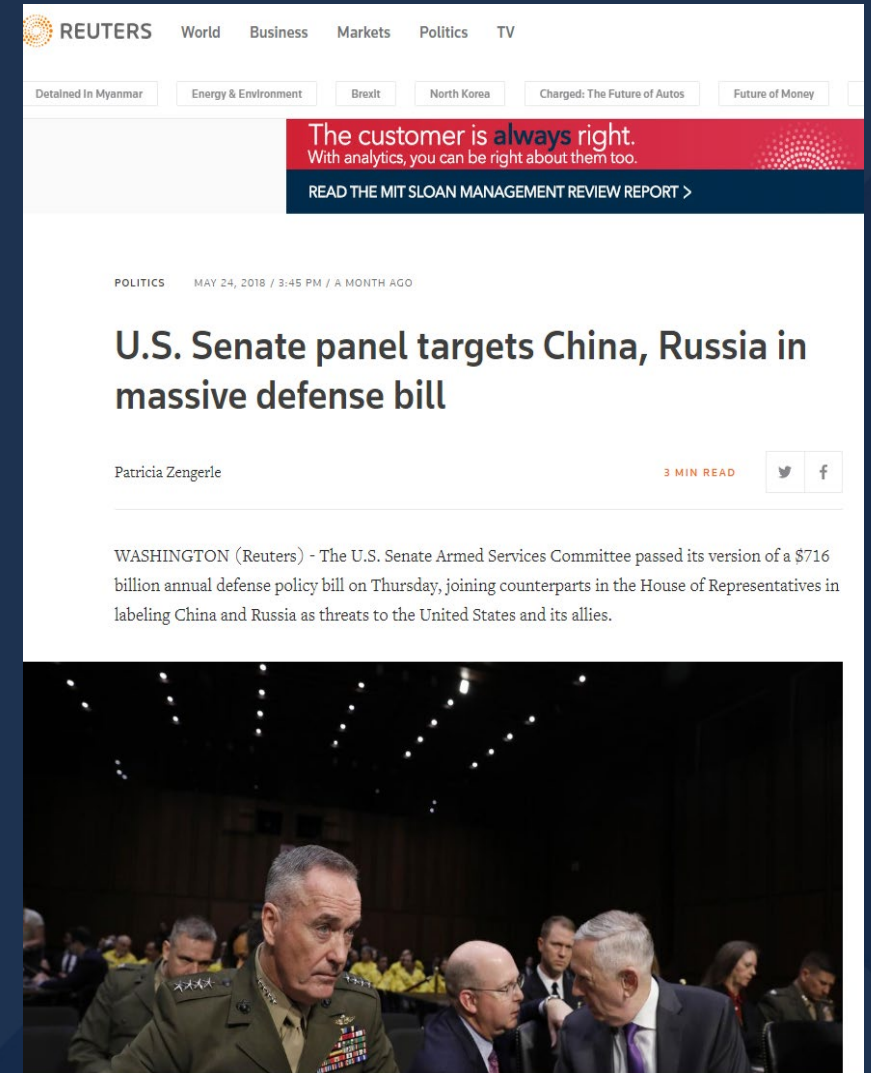


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Personal Finance

MAY 24, 2018 NDAA DEFENSE BILL HAS IMPLICATIONS & EQUIPMENT USE RESTRICTIONS ON HUAWEI AND ZTE

... The 2019 National Defense Authorization Act, or NDAA, includes measures targeting the two “strategic competitors,” including a clampdown on trade rules and a **ban on the Defense Department dealing with any entity that uses telecommunications equipment or services from Chinese companies Huawei Technologies and ZTE Corp.**



JUNE 11, 2018 DEPARTMENT OF STATE VISA CHANGE


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Chinese graduate students in some fields may now receive 1-year visas. ONEDAY0619/SHUTTERSTOCK.COM

More restrictive U.S. policy on Chinese graduate student visas raises alarm

By Jeffrey Mervis | Jun. 11, 2018, 12:10 PM

Reversing yet another policy of the previous administration, the U.S. Department of State today began applying tougher restrictions on some Chinese graduate students. The new policy shortens from 5 years to 1 year the duration of visas for those planning to study aviation, robotics, and advanced manufacturing. Although the ostensible reason for the change is to improve national security, U.S. university officials see it as the latest attack on graduate education and the free flow of scientific knowledge.

The revised visa policy was initially reported last month by various media outlets and confirmed last week by a senior departmental official during a **hearing on student visas by a Senate panel** on border security and immigration. The title of the hearing paints the dilemma in stark terms: "Student Visa Integrity: Protecting Educational Opportunity and National Security."

- More and more visa approvals are requiring detailed information on the specific area of research, source of funding and restricted technology access
- Contract and grants are a major source of funding for all student, staff and faculty researchers at UCSD
- Identifying publication and/or foreign national restrictions in calls and awards is critical

<http://www.sciencemag.org/news/2018/06/more-restrictive-us-policy-chinese-graduate-student-visas-raises-alarm>

JUNE 18, 2018

WHITE HOUSE REPORT ON CHINA MENTIONS UNIVERSITIES



How China's Economic Aggression Threatens the Technologies and Intellectual Property of the United States and the World



White House Office of Trade and Manufacturing Policy
June 2018

<https://www.whitehouse.gov/wp-content/uploads/2018/06/FINAL-China-Technology-Report-6.18.18-PDF.pdf>

JUNE 20, 2018 WASHINGTON POST

Josh Rogin • Opinion

Congress wants DeVos to investigate Chinese research partnerships on American campuses

By Josh Rogin June 20 [Email the author](#)

- They want DeVos to investigate the [Huawei Innovation Research Program](#) and other programs through which Huawei partners with institutes of higher education across the country.
- “We believe these partnerships may pose a significant threat to national security and this threat demands your attention and oversight,” ...
- The lawmakers told DeVos that she should convene a task force to investigate these partnerships...
- **The lawmakers want universities partnering with Huawei to hand over the contracts and details, especially at universities that receive federal funding or participate in research dealing with classified information. If they don’t comply, Congress could hold related funding as leverage.**

JUNE 21, 2018 ASSOCIATED PRESS

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BUSINESS

Feds: Man smuggled anti-submarine warfare devices to China



The Associated Press

June 21, 2018 07:35 PM
Updated June 21, 2018 07:36 PM

BOSTON — Authorities say a Chinese national has been charged with conspiring with a Chinese military research institute to illegally export U.S. goods used in anti-submarine warfare to China.

Federal prosecutors say 41-year-old Shuren Qin, who lives in Wellesley, Massachusetts, was arrested Thursday. He's charged with visa fraud and conspiring to violate U.S. export regulations.

Court documents say Qin illegally exported nearly 80 devices used to detect and monitor sound underwater to a Chinese military research institute affiliated with the People's Liberation Army.

The documents say Qin exported the goods to Northwestern Polytechnical University by lying to the U.S. supplier and concealing the true recipient. Such exports are prohibited without a license.

Increase in
media
reports of
university
involvement
in illegal
exports and
IP theft

AUGUST 13, 2018

EXPORT CONTROL REFORM ACT OF 2018

Sections 1741-1793 of NDAA FY19

Enforcement and Guidance for academic institutions

(7) **enforce** the controls through means such as regulations, requirements for compliance, lists of controlled items, lists of foreign persons who threaten the national security or foreign policy of the United States, and **guidance** in a form that facilitates compliance by United States persons and foreign persons, **in particular academic institutions**, scientific and research establishments, and small- and medium-sized businesses.

<https://www.congress.gov/bill/115th-congress/house-bill/5515/text>

AUGUST 13, 2018

EMERGING TECHNOLOGIES NDAA FY19

Section 1758 REQUIREMENTS TO IDENTIFY AND CONTROL THE EXPORT OF EMERGING AND FOUNDATIONAL TECHNOLOGIES

New Interagency Group that would receive inputs from public info, classified info (ODNI), CFIUS review and the Emerging Technologies and Research Advisory Committee (ETRAC)

may revise the duties to include identifying trends in—

- (i) the **ownership by foreign persons and foreign governments of such technologies;**
- (ii) the types of transactions related to such technologies engaged in by foreign persons and foreign governments;
- iii) the **blending of private and government investment in such technologies;** and
- (iv) **efforts to obfuscate ownership of such technologies** or to otherwise circumvent the controls established under this section.

<https://www.congress.gov/bill/115th-congress/house-bill/5515/text>

AUGUST 23, 2018 NIH CONCERNS ON FOREIGN INFLUENCE

NIH Investigating Foreign Influence on Research

By [Andrew Kreighbaum](#) // August 24, 2018

0 COMMENTS

National Institutes of Health director Francis Collins said Thursday that the agency is investigating multiple research institutions where researchers failed to disclose improper support from foreign governments.

In a [letter](#) to grant recipient institutions, Collins said foreign entities had mounted "systematic programs" to influence NIH research. The agency's concerns include the sharing of information on grant applications with foreign entities as well as failures to disclose financial support from foreign governments.

Collins also spoke about those research issues at a [hearing](#) of the Senate Health, Education, Labor and Pensions Committee, which oversees the agency.

NIH is responding by working with other government agencies and professional organizations to push for better reporting on sources of research support and improve intellectual property.

The letter also encouraged research institutions to reach out to the FBI about information involving grant applications or awards.

From Inside
Higher Ed

<https://www.nih.gov/about-nih/who-we-are/nih-director/statements/statement-protecting-integrity-us-biomedical-research>

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THE NIH DIRECTOR

The NIH Director

August 23, 2018

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Statement on Protecting the Integrity of U.S. Biomedical Research



NIH research is built on the bedrock principles of scientific excellence, unassailable integrity, and fair competition. NIH's commitment to these principles is unwavering. We have long understood, however, that the robustness of the biomedical research enterprise is under constant threat by risks to the security of intellectual property and the integrity of peer review. This knowledge has shaped our existing policies and practices, but these risks are increasing. Three areas of concern have emerged: 1) failure by some researchers at NIH-funded institutions to disclose substantial contributions of resources from other organizations, including foreign governments, which threatens to distort decisions about the appropriate use of NIH funds; 2) diversion of intellectual property in grant applications or produced by NIH-supported biomedical research to other entities, including other countries; and 3) in some instances, sharing of confidential information by peer reviewers with others, including in some instances with foreign entities, or otherwise attempting to influence funding decisions.

While we depend on the major national security agencies and the Department of Health and Human Services' broad national security efforts to protect our national security interests, NIH and the U.S. biomedical research community at large have a vested interest in mitigating these unacceptable breaches of trust and confidentiality that undermine the integrity of U.S. biomedical research.

In response, NIH will work with other government agencies, NIH-funded academic institutions, U.S. professional organizations, and a working group of the Advisory Committee to the (NIH) Director to identify robust methods to: 1) improve accurate reporting of all sources of research support, financial interests, and affiliations; 2) mitigate the risk to intellectual property security while continuing NIH's long tradition of collaborations, including with foreign scientists and institutions; and 3) explore additional steps to protect the integrity of peer review.

The U.S. biomedical enterprise sets the standard for discovery and innovation excellence for the rest of the world. Our leadership position is made possible because the overwhelming majority of researchers participating on NIH grants, whether U.S. or foreign-born, are honest, hard-working contributors to the advancement of knowledge that benefits us all.

OCTOBER 24 2018

CONCERNS OVER TALENTS PROGRAMS

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nature

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China hides identities of top scientific recruits amidst growing US scrutiny

Chinese researchers fear that affiliation with the high-status Thousand Talents scheme could make them targets of FBI investigations.

Smiti Mallapaty



US congressman Lamar Smith accused China of planting sleeper agents in US universities to steal scientific breakthroughs at an April 2018 hearing. Credit: Scott J. Ferrell/Congressional Quarterly/Getty

China's flagship science talent recruitment programme, the Thousand Talents Plan, has gone underground amidst intensifying scrutiny by United States government agencies for China's suspected role in the theft of US technologies and intellectual property.

A climate of fear has engulfed Chinese scientists in both countries worried that association with the previously prestigious programme will make them targets of US investigations, including by the Federal Bureau of Investigation (FBI).

RELATED ARTICLES

US-Chinese trade war p
in the cross hairs

China's plan to recruit t
researchers

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SUBJECTS

Politics Research man

<https://www.nature.com/articles/d41586-018-07167-6>

NOVEMBER 2, 2018

DOJ CHINA INITIATIVE FACT SHEET

Develop an enforcement strategy concerning non-traditional collectors (e.g., researchers in labs, **universities**, and the defense industrial base) that are being coopted into **transferring technology contrary to U.S. interests**;

Educate colleges and universities about potential threats to academic freedom and open discourse from influence efforts on campus;

Implement the Foreign Investment Risk Review Modernization Act (FIRMA) for DOJ (including by working with Treasury to **develop regulations** under the statute and prepare for increased workflow);

Identify opportunities to better address supply chain threats, especially ones impacting the **telecommunications sector**, prior to the transition to **5G networks**;

<https://www.justice.gov/opa/speech/file/1107256/download>

Define emerging technologies that are not now controlled for export, but should be because they are essential to the national security of the United States.

- (i) “biotechnology”;
- (ii) “artificial intelligence”;
- (iii) “Position, Navigation, and Timing (PNT) technology”;
- (iv) “microprocessor technology”;
- (v) “advanced computing technology”;
- (vi) “data analytics technology”;
- (vii) “quantum information and sensing technology”;
- (viii) “logistics technology”;
- (ix) “additive manufacturing”;
- (x) “robotics”;
- (xi) “brain-computer interfaces”;
- (xii) “hypersonics”;
- (xiii) “advanced materials”; and
- (xiv) “advanced surveillance technologies.”

DECEMBER 13, 2018

NIH WORKING GROUP FOR FOREIGN INFLUENCES ON RESEARCH INTEGRITY REPORT

The Advisory Committee to the Director working group for Foreign Influences on Research Integrity was established to develop recommendations to address behaviors related to these efforts in ways that build and continue important and successful relationships with foreign scientists in all countries while simultaneously protecting America's research integrity.

With the importance of upholding relationships with foreign nationals in mind, the ACD working group makes several recommendations to the ACD, under the umbrella of three main themes:

- Communication and Awareness: Opportunities where existing procedures are in place but in need of education, clarification, or increased attentiveness;
- Risk Mitigation: Opportunities for change or enhancement of existing tools that safeguard research integrity; and
- Monitoring, Actions, and Consequences: Opportunities for ongoing monitoring, verification, trust-building, and remediation.

Universities, institutions, and organizations that apply for and receive NIH grant money must work together with NIH to identify and allow for best practices to allow for institutional variation in implementing these recommendations.

JANUARY 4, 2019 PROPOSED OFFICE OF CRITICAL TECH & SECURITY

Mark R. Warner
US Senator from the Commonwealth of Virginia

Meet Mark

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PRESS RELEASES



Warner, Rubio Introduce Bipartisan Legislation to Combat Technology Threats From China

Jan 04 2019

WASHINGTON— Today, the Vice Chairman of the Senate Select Committee on Intelligence Sen. Mark R. Warner (D-VA) and Committee member Sen. Marco Rubio (R-FL) introduced bipartisan legislation to help combat tech-specific threats to national security posed by foreign actors like China and ensure U.S. technological supremacy by improving interagency coordination across the U.S. government. To do this, the bill creates an Office of Critical Technologies & Security at the White House responsible for coordinating across agencies and developing a long-term, whole-of-government strategy to protect against state-sponsored technology theft and risks to critical supply chains.

"It is clear that China is determined to use every tool in its arsenal to surpass the United States technologically and dominate us economically. We need a whole-of-government technology strategy to protect U.S. competitiveness in emerging and dual-use technologies and address the Chinese threat by combating technology transfer from the United States," **said Sen. Warner, a former technology and telecommunications executive.** "We look forward to working with the Executive Branch and others to coordinate and respond to this threat."

"China continues to conduct a coordinated assault on U.S. intellectual property, U.S. businesses, and our government networks and information with the full backing of the Chinese Communist Party," **said Sen. Rubio.** "The United States needs a more coordinated approach to directly counter this critical threat and ensure we better protect U.S. technology. We must continue to do everything possible to prevent foreign theft of our technology, and interference in our networks and critical infrastructure. By establishing the Office of Critical Technologies and Security, this bill will help protect the United States by streamlining efforts across the government. I look forward to working with my colleagues and the Administration to enact this legislation and guard against these national security threats."

China and other nations are currently attempting to achieve technological and economic superiority over the United States through the aggressive use of state-directed or -supported technology transfers. At the same time, the U.S. is also facing major challenges to the integrity of key supply chains as a result of reliance on foreign products that have been identified as national security risks. A national response to combat these threats and ensure our national security has, to date, been hampered by insufficient coordination at the federal level.

<https://www.warner.senate.gov/public/index.cfm/pressreleases?ID=9D405E99-2E31-4A2D-A79F-9F3FF3B32122>

FEBRUARY 1, 2019 DEPARTMENT OF ENERGY MEMO

Energy Department to Ban Foreign Talent- Recruitment Programs

U.S. takes aim at programs run by China and others it says can threaten national security

Updated Feb. 1, 2019 6:52 p.m. ET



In a memo issued Friday, the department said it would require all of its personnel, contracted scientists and future grant recipients to declare any connections to programs from countries it determines as “sensitive.” Employees with the links will be asked to either sever those ties or resign, senior department officials said.

The department oversees 17 national laboratories conducting advanced research in fields including nuclear physics and supercomputing.

“This action’s being taken to protect U.S. national security interests and scientific integrity,” Dan Brouillette, deputy energy secretary, told The Wall Street Journal. “You’re either going to work for us or work for them.”

Wall Street Journal

<https://www.wsj.com/articles/energy-department-to-ban-foreign-talent-recruitment-programs-11549052674>

AMERICAN UNIVERSITIES RESPOND

- AAU/APLU Science and Security Working Group
- Campus meetings with FBI regarding foreign influence per NIH advice
- Memos issued to campuses on transparency in COI and COC reporting of foreign components
- NIH Working Group on Foreign Influence participation by University leaders
- AAU/APLU Survey on Best Practices to Address Security Threats and Undue Foreign Influence on Campus
- American Council on Edu letter to Dept. of Ed. clarifying reporting on foreign gifts and contracts (Section 117)
- Deans Roundtable to provide input to DOD Office of Basic Research on Foreign Person Participation in DOD sponsored research
- DARPA meeting with University leaders on emerging technologies
- University federal relations officers meeting with Hill and Agencies to provide information on what Universities are doing to address these concerns

WHAT CAN WE DO TO PROTECT UC SAN DIEGO?

- Follow established UC and UC San Diego Procedures
 - UC Policies on COI, COC and External Research outline responsibilities for reporting
 - Our existing procedures for proposals, agreements, purchasing and visiting scholars are in place to comply with regulations and alert us to address risks
 - Use visual compliance for screening foreign collaborators, including visitors, funding entities, purchases or shipments
 - Restricted parties lists are being updated every few days by the USG
 - New restricted party screening video in UC learning
- Escalate any requests for information from federal authorities on national security or export controls to Brittany Whiting, Export Control Director brwhiting@ucsd.edu
858-534-4175

FOREIGN COMPONENT- NIH DEFINITION

- The performance of any significant scientific element or segment of a project outside of the United States, either by the recipient or by a researcher employed by a foreign organization, whether or not grant funds are expended.
- Activities that would meet this definition include, but are not limited to,
 - (1) the involvement of human subjects or animals,
 - (2) extensive foreign travel by recipient project staff for the purpose of data collection, surveying, sampling, and similar activities, or
 - (3) any activity of the recipient that may have an impact on U.S. foreign policy through involvement in the affairs or environment of a foreign country.
- Examples of other grant-related activities that may be significant are:
 - collaborations with investigators at a foreign site anticipated to result in co-authorship;
 - use of facilities or instrumentation at a foreign site; or
 - receipt of financial support or resources from a foreign entity.

Foreign travel for consultation is not considered a foreign component.

UC San Diego

RESEARCH COMPLIANCE AND INTEGRITY

Conflict of Interest (COI) Office

Jennifer J. Ford
Director

THE ROLE OF THE CONFLICT OF INTEREST OFFICE



The UC San Diego Conflict of Interest Office, also known as the COI Office, role is to provide faculty and staff assistance in assessing circumstances under which their outside activities or financial interests may inappropriately conflict with their responsibilities to the University.

CONFLICT OF INTEREST (COI) OFFICE SERVICES

- Reviews disclosures of financial interests from University faculty and staff
- Ensures compliance with all applicable regulations
- Serves as a resource to University faculty, staff and institutional offices



UNIVERSITY EMPLOYMENT COI

- Faculty APM 025/671: Conflict of Commitment
 - Not managed by the COI Office
- Staff Conflict of Interest:
 - PPSM-82
- Provide guidance for COI
 - Starting companies
 - Consulting with companies



WHEN ARE CONFLICT OF INTEREST (COI) DISCLOSURES REQUIRED?

COI Research and Other Related Activity Disclosures

Category	Agency	Examples
Sponsored Research	Federal	National Health Institute (NIH) National Science Foundation (NSF)
	Non-Federal	For-Profit Non-Profit*
Other Related Activity	Non-Federal	Gifts Material Transfer Agreements (MTA) Service Unfunded

* There are sponsors exempt from the disclosure requirement

WHAT CONSTITUTES A POTENTIAL RESEARCH COI?

Type of Interests*	Examples
Income/Payments	Salaries, Consulting, Honoraria
Position	Founder, Partner, Board of Directors, Scientific Advisory Board, Employee
Equity / Ownership Interest	Stocks, Bonds, Stock Options
Gifts	From outside entity
Loans	Money loaned to outside entity
Travel Reimbursement/Payments	From outside entity
Intellectual Property	Non-UC royalties

*Applies to the Employee, Spouse, Registered Domestic Partner, and Dependent Children

WHEN AND WHO MUST DISCLOSE FOR COI?

Funding Entity Sponsor	Common Sponsors	When to Disclose	Who Must Disclose
Public Health Services (PHS)	NIH or those that have adopted FCOI	Initial submission, Change in funding, Addition of new personnel, Change in financial interest, No cost extension, At least annually	Principal Investigator (PI), Project Director, Senior/Key Personnel, and Others who direct or can materially influence the research, or who are responsible for the design, conduct, and reporting of such research
Federal Non-PHS*	NSF, CIRM and UC Programs	Initial submission, Change in funding, Change in financial interest	Principal Investigator (PI), and All other individuals who have the responsibility for the design, conduct or reporting of research
Non-Federal*	Non-Profit For-Profit	Initial submission, Additional funding, Renewal proposal Change in financial interest	Principal Investigator (PI) Studies involving <u>human subjects</u> , PI and any study personnel with a financial interest in an entity that would reasonably appear to be affected by the research
Unfunded Projects Clinical Research	Internal unrestricted	Initial submission to IRB	PI with a financial interest in an entity that would reasonably appear to be affected by the research

*There are sponsors exempt from the disclosure requirement: all non-profit, tax-exempt educational institutions, and those on the list (on COI Website).

Important: Update of Financial Interests for Sponsored Activities within 30 days

THRESHOLDS FOR DISCLOSURE?

Funding Entity Sponsor	Income Compensation	Ownership Position	Investment Equity	Travel reimbursement	Loans	Gifts	Intellectual Property
Public Health Services (PHS)	publicly traded > \$5,000	Any	publicly traded > \$5,000	> \$5,000	> \$5,000	> \$5,000	Any excludes UC
	non-publicly traded > \$5,000		non-publicly traded ≥ \$0				
Federal Non-PHS 9510	> \$10,000	Any	> \$10,000 or > 5% owner	≥ \$0	> \$10,000	> \$10,000	Any excludes UC
Non-Federal 700U	>\$500	Any	>\$2,000	≥ \$0	≥ \$500	≥ \$50	Any excludes UC

Important: Update of Financial Interests for Sponsored Activities within 30 days

COI DISCLOSURE DETERMINATION

Who is the Sponsor?	Which Disclosure Form?	What to Disclose?	Who decides if the research and the interests are related?
Public Health Services (PHS) (i.e. NIH and those who have adopted PHS)	PHS	Disclose all interests related to the discloser's Institutional Responsibilities*	Institution
Federal Non-PHS (i.e. NSF, CIRM, UC Programs)	9510	Disclose any interests related to the work to be conducted under the proposed project	Discloser
Non-Federal (For-Profit or Non-Profit)**	700U	Disclose any interests with the sponsor(s)	Institution

* Reasonably appears *to be related to or is in the same field of expertise as your Institutional Responsibilities*.

** Includes research and other related activities (gifts, service agreements, MTAs, unfunded projects, etc.)

SUBMISSION OF COI DISCLOSURE FORMS

PHS Form submitted at time of proposal and supplement at NOA
9510 and 700U must be completed, signed and dated at time of proposal

Funding Entity Sponsor	Disclosure Form Required with Initial Submission	Additional Form Required if Positive	When does COI Office review?
Public Health Services (PHS) (NIH and those who have adopted PHS)	PHS Form	Supplement	Notice of Award
Federal Non-PHS (NSF, CIRM, UC Programs)	9510	Addendum	Proposal submission
Non-Federal (For-Profit or Non-Profit)**	700U	Addendum	Proposal submission

WHAT HAPPENS IF THERE IS A POSITIVE COI DISCLOSURE?

If a financial interest exists:

- Investigator's financial disclosure forms must be reviewed by the COI Office
- Depending on the scope and nature of the disclosure and/or project the conflict of interest may be managed by the Independent Review Committee (IRC) on Conflict of Interest
- Various institutional offices receive notice that the COI review must be completed before the project can move forward and funds allocated

COMMON IRC MANAGEMENT STRATEGIES

- Disclosure of interest(s) in presentations and publications
- Ensuring the protection of students and postdoctoral scholars by disclosure of interests or appointment of a co-advisor
- Disclosure of interest(s) in the Informed Consent Form, if applicable
- Monitoring of the project by the Conflict of Interest Management Subcommittee (COIMS)
- Discontinue consulting and any other recompensed activities during the course of a research project

REMINDERS

- Email completed, signed and dated COI Disclosure forms to coiforms@ucsd.edu with ePD #
- STTR/SBIR if a University researcher wants to be the PI for the Company, contact the COI Office
- Disclose financial interests including foreign Universities and foreign governments consistent with the regulations of the applicable COI form
- Researchers need to provide updates of financial interest within 30 days
- COI question for interests with Subrecipients in Marketplace



CONFLICT OF COMMITMENT AND CONFLICT OF INTEREST INTERSECTION

- The University recognizes that there is value in faculty engaging in outside professional activity
 - Outside Professional Activities: Activities that are within a faculty member's area of professional, academic expertise and that advance or communicate that expertise through interaction with industry, the community, or the public
- Policies APM 025, APM 028, and APM 671 provide the parameters to balance the faculty member's University obligations and their outside professional activities
 - APM 028 was revised in February as guidelines for disclosure and review

CONFLICT OF COMMITMENT AND CONFLICT OF INTEREST INTERSECTION (CONTINUED)

- Some outside activities however may interfere with a faculty member's professional obligations to the University as well as raise conflict of interest concerns
- Considerations:
 - Proposed activity, interests, time involved
 - Is activity related to ongoing research
 - Intellectual property interests
 - Update of financial interests

CONFLICT OF COMMITMENT (COC) AND CONFLICT OF INTEREST (COI)

	<u>Conflict of Commitment</u>	<u>Conflict of Interest</u>
Policies	APM 025 / APM 671	UCSD PPM 200-13, APM 028, OP PHS and NSF*
Disclosure Forms	Category I (prior approval) and II	Dependent on outside funding entity**
Timing	Category I: Prior to Engagement Category II: Annually	Proposal and/or award stages and then dependent on funding
Responsible Offices	Academic Affairs	Conflict of Interest Office

Similarity: Engagement with outside activities

* There are many COI policies, see <http://blink.ucsd.edu/sponsor/coi/policies.html>

** Disclosure may be required for internal funding when Human Subjects are involved

RECOMMENDATIONS



- Submit Conflict of Interest (COI) Disclosures
- Submit Conflict of Commitment (COC) Report
 - Be transparent in federal contracts and grants about any affiliations with foreign entities
 - Disclose in proposals (biosketches and other support)
 - Disclose in progress reporting

ANNOUNCEMENT: KUALI COI

Kuali COI is a user friendly web based system to create electronic conflict of interest disclosure

Under the Enterprise System Renewal (ESR) program Kuali COI module was procured to:

- Simplify
- Collect
- Process
- Access

Investigator(s) financial interests and outside activities

For PHS projects, submit one disclosure per year

Kuali COI will integrate with Kuali Research



SDSC's Gordon Supercomputer. Photo: Erik Jepsen, UCSD

CONTACT THE CONFLICT OF INTEREST (COI) OFFICE

Email Questions: info-coi@ucsd.edu
Email COI Forms: coiforms@ucsd.edu
Telephone: (858) 534-6465
COI Website: <http://coi.ucsd.edu>



Jennifer Patterson

PHS Support



Xuemei Wang

PHS Support



Albert Carazolez

Non-PHS and 700U Support



Dena Demos

COI forms intake



Jennifer Ford

Director

UC San Diego

RESEARCH COMPLIANCE AND INTEGRITY

Institutional Animal Care and Use Committee (IACUC) Office

Kristen Anderson-Vicino
Director

UC San Diego

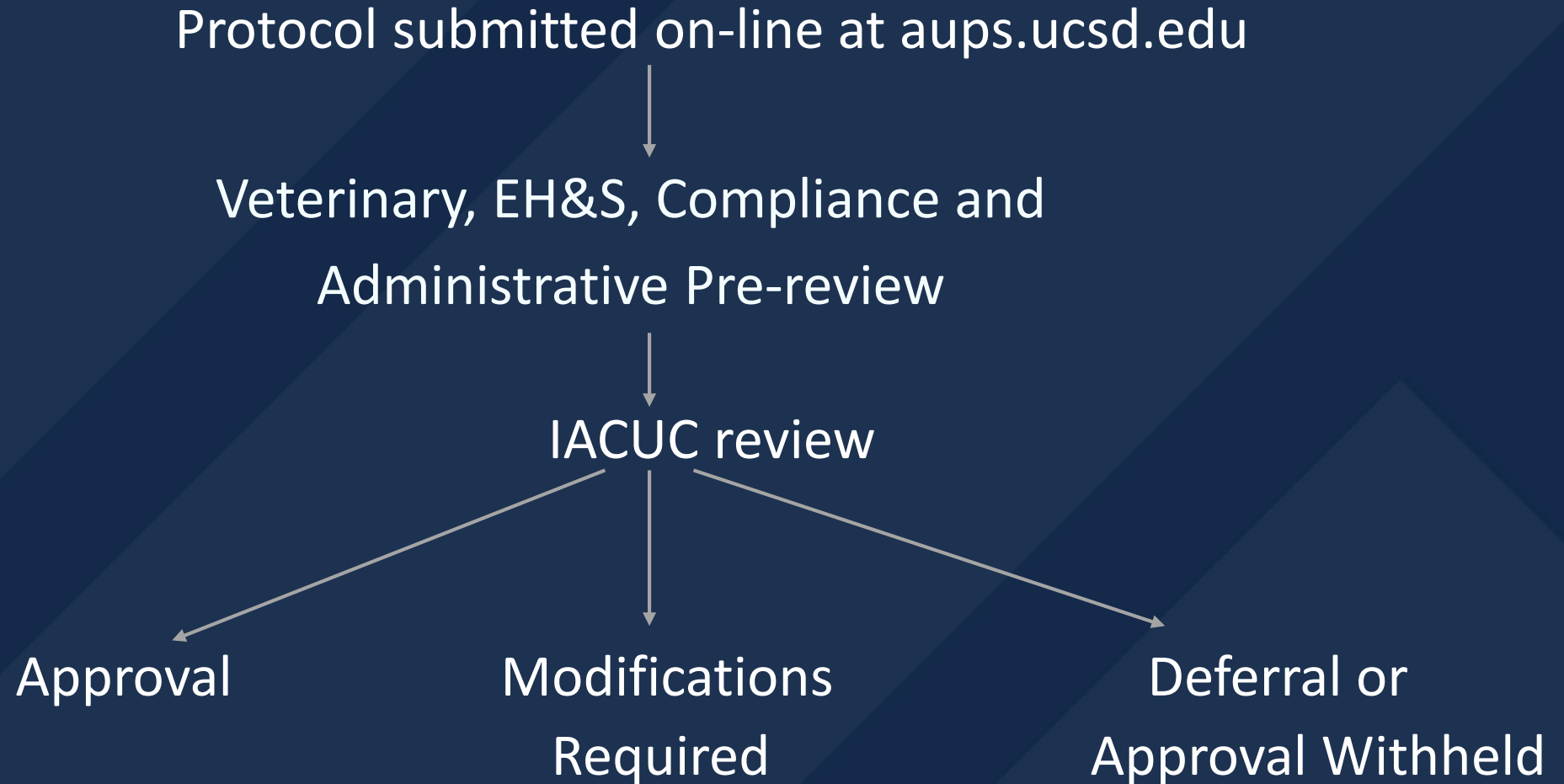
WHAT IS THE IACUC?

- Mandated by federal law that any institution doing animal research must have this committee
- Members include UCSD faculty members from all schools and departments using animals as well as non-affiliated members
- Oversees the University's animal care and use program
- Reviews and approves all animal research protocols
- Inspects animal facilities and laboratories
- Oversees the training and educational programs for researchers working with animals
- Investigates animal welfare concerns

IACUC OFFICE CONTACT INFORMATION

- <http://blink.ucsd.edu/sponsor/iacuc/>
- IACUC Office Phone: 858-534-6069
- IACUC Email: iacuc@ucsd.edu
- All information that a new Principal Investigator (PI) needs to register and use the online IACUC system is on the website
- Online website is SSO-secured
- If a PI wishes to begin working on his/her protocol prior to receiving his/her appointment, he/she will need to be sponsored by the department in order to receive an affiliate SSO account

PROTOCOL REVIEW PROCESS



IACUC PROTOCOL REVIEW

- Mechanisms by which protocols may be reviewed are defined by federal regulations:
 - Full Committee Review (FCR)
 - Designated Member Review (DMR)
 - Designated Member Administrative Review (DMA)
 - Veterinary Verification and Consultation (VVC)
- The mechanism for review depends on the nature of the protocol or amendment, but the IACUC always attempts to review protocols by the fastest mechanism in order to facilitate research as work may not commence until the protocol or amendment has been approved

PRINCIPAL INVESTIGATOR ELIGIBILITY

- Eligibility to serve as a PI on an animal use protocol is the same as the University's requirements for eligibility to be a PI on a grant (PPM 150-10)
- An approval for an exception must be approved by the appropriate Vice Chancellor prior to eligibility to be a PI on an animal use protocol
- A fully executed copy of the PI exception form needs to be provided to the IACUC Office before the IACUC will approve the PI's protocol

REQUIRED TRAINING

- All PIs and personnel performing research and teaching involving animals at UCSD are required to complete the on-line "Orientation to Animal Research at UCSD" class
- The IACUC will also require additional training for each individual, depending on their prior training and experience with animals
- Refresher training is required of all PIs and personnel once every three years and usually coincides with the year of our triennial AAALAC accreditation site visit

AAALAC INTERNATIONAL ACCREDITATION

- AAALAC International is a private, nonprofit organization that promotes the humane treatment of animals in science through voluntary accreditation and assessment programs.
- The University of California Office of the President (UCOP) Policy requires that all UC campuses be AAALAC accredited.
- UC San Diego's accreditation site visit will take place this Fall 2019



INTER-INSTITUTIONAL WORK

- There are a number of special considerations for Inter-institutional work involving animals. The UC San Diego IACUC has an Inter-Institutional Policy which describes various arrangements and how they should be handled: <http://blink.ucsd.edu/files/sponsor-tab/iacuc/Policy%2021%20Interinstitutional.pdf>
- Animals owned by UCSD (bought with funding to a UCSD PI) may only be used/housed at AAALAC-accredited institutions, see <https://www.aaalac.org/accreditedorgsDirectorySearch/index.cfm>

IACUC CONTACT INFORMATION

- IACUC Office Website: <http://blink.ucsd.edu/sponsor/iacuc/>
Email Questions: iacuc@ucsd.edu
Telephone: (858) 534-6069
- Kristen Anderson-Vicino, Director, kca002@ucsd.edu

UC San Diego

RESEARCH COMPLIANCE AND INTEGRITY

Research Misconduct

Angela Fornataro McMahon

Executive Director, Research Compliance and Integrity

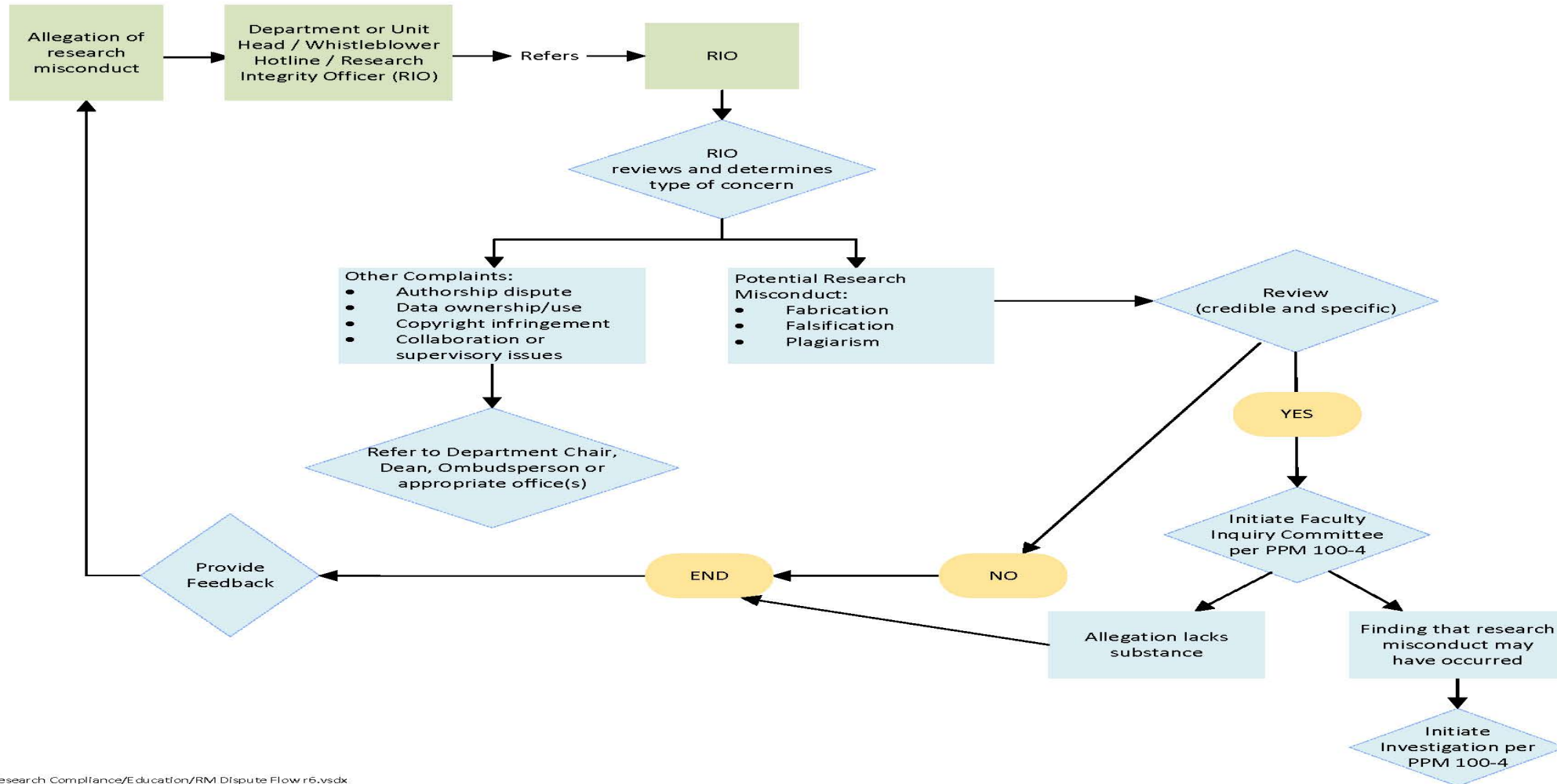
UC San Diego

RESEARCH MISCONDUCT

- Research misconduct per federal regulations:
 - Fabrication: Making up data or results and recording or reporting them
 - Falsification: Manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record
 - Plagiarism: The appropriation of another person's words, ideas, processes or research results without acknowledgement, and passing them off as one's own
- Questionable research practices should be resolved by the appropriate department/research group. Examples include good clinical practices violations, authorship disputes, attribution of credit, data access and use, differences of opinion or honest error. The VCR will provide assistance if necessary.

RESEARCH MISCONDUCT FLOW

Research Misconduct Review Process



RESEARCH MISCONDUCT DATA

- Office of Research Integrity 2008 – 2017
 - Receives on average of 278 allegations per year
 - Opens on average 32 cases per year
 - In 36% of cases there are Research Misconduct findings
 - 49% Fabrication and Falsification
 - 38% Falsification
 - 4% Fabrication and Plagiarism
 - 3% Plagiarism
 - 2% Other combinations (3% Null)
 - The number of reported cases, cases opened and findings have decreased dramatically over the past several years

RESEARCH MISCONDUCT DATA (CONTINUED)

- Office of Research Integrity 2008 – 2017
 - Research Misconduct Findings by Rank:
 - 26% Postdoctoral Scholar
 - 17% Assistant Professor
 - 15% Principal Investigators (not defined)
 - 10% Students and Research Technician/Associate/Assistant
 - 8% Professor and Unknown
 - 6% Associate Professor
 - 27% female, 67% male and 6% unknown

COMMON RESEARCH MISCONDUCT QUESTIONS

- Common questions from the Respondent
 - Who knows about the allegation
 - Why do you have to sequester my computers, files, etc.
 - How long will this process take
 - What are the possible outcomes

UNANNOUNCED VISITS BY FEDERAL AND STATE AGENCIES

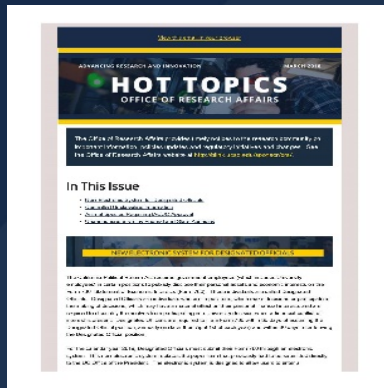
- UC San Diego can expect site visits by outside agencies as part of routine oversight activities and for specific ongoing investigations
- The University's practice is to cooperate with outside investigating agencies, while protecting the rights and privacy of the students, faculty, staff and research subjects
- **Promptly contact Research Compliance and Integrity** who will provide assistance or alert appropriate institutional offices

For additional information and FAQs, please see

<https://blink.ucsd.edu/research/policies-compliance-ethics/index.html>

COMMUNICATIONS

- Research Compliance and Integrity Helpline: (858) 822-4939, rci@ucsd.edu
- Conflict of Interest Helpline: (858) 534-6465. info-coi@ucsd.edu
- Export Control Helpline: (858) 246-3300, export@ucsd.edu
- IACUC Helpline: (858) 534-6069, iacuc@ucsd.edu
- Hot Topics and Newsletters:



- Website: <http://blink.ucsd.edu/sponsor/rci/news.html>
- To be added to the RCI list serv, please email rci@ucsd.edu

UC San Diego

RESEARCH COMPLIANCE AND INTEGRITY

RESOURCES:

Research Compliance and Integrity:

Phone: (858) 822-4939

Email: rci@ucsd.edu

Website: rci.ucsd.edu

Executive Director: Angela Fornataro McMahon

IACUC:

Phone: (858) 534-6069

Email: iacuc@ucsd.edu

Website: blink.ucsd.edu/sponsor/iacuc

Director: Kristen Anderson-Vicino

Conflict of Interest:

Phone: (858) 534-6465

Email: info-coi@ucsd.edu

Website: blink.ucsd.edu/sponsor/coi

Director: Jennifer J. Ford

Export Control, DURC and Facility Security:

Phone: (858) 246-3300

Email: export@ucsd.edu

Website: blink.ucsd.edu/sponsor/exportcontrol

Director: Brittany Whiting