

UC San Diego

RESEARCH COMPLIANCE AND INTEGRITY

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RESEARCH COMPLIANCE AND INTEGRITY

UC San Diego

Office of Research Compliance and Integrity

- Oversight and Responsibility for:
 - Conflict of Interest (COI) Office
 - Dual Use Research of Concern (DURC)
 - Export Control and Facility Security
 - Institutional Animal Care and Use Committee (IACUC)
 - Research Integrity

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RESEARCH COMPLIANCE AND INTEGRITY

Conflict of Interest (COI) Office

Jennifer J. Ford

Research Compliance and Integrity

Conflict of Interest Office

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RESEARCH COMPLIANCE AND INTEGRITY

Conflict of Interest (COI) Office



- **Assists employees in assessing circumstances under which their outside activities or interests may inappropriately conflict with their responsibilities to the University**
 - Seeks to maintain a reasonable balance between competing interests
 - Promotes transparency and disclosure as a means to identify interests that might bias research
 - Provides mechanisms to manage the collaborative research partnerships between the Government, the University, and private industry

Definition of Conflict of Interest

- The term “conflict of interest” (COI) refers to situations in which financial or other personal considerations may compromise or *have the appearance of compromising* an employee’s professional judgment in administration, management, teaching, research and other professional activities
 - In the University environment, we are often moving so fast that we may not be aware of the actions that might create COI situations



What Constitutes a Potential COI?

■ Potential COI's:

- Income/Payments: Salaries, Consulting, Honoraria, etc., from an outside entity
- Position: Founder, Partner, Board of Directors, Scientific Advisory Board, Employee, etc.
- Ownership Interest: Stocks, Bonds, Stock Options
- Gifts
- Loans
- Travel Reimbursement/Payments
- Intellectual Property

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

What is Subject to COI Disclosure? Research or Other Related Activities

- **Sponsored Research** (Basic, Applied, Animal, Human)
 - Federal:
 - NIH and NSF
 - Other agencies who have adopted the federal requirements (including sub-awards)
 - Non-Governmental
 - Non-Profit
 - For-Profit
- **Other Related Activities** (Non-Governmental)
 - Gifts
 - Lab Service Agreements (LSA)
 - Institutional Service/Consulting Agreements (ISA/ICA)
 - Material Transfer Agreements (MTA)

When and Who Must Disclose for COI?

Funding Entity	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 or those that have adopted	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](#))

Which Form to submit for COI Disclosure?

Funding Entity	Common Sponsors	Types of Activities	Initial Disclosure Form	Additional Disclosure (if mark yes)
Public Health Services (PHS)	NIH or those that have adopted FCOI	Research, Center, Career, Fellowships, Training	PHS Form	Supplement
Federal Non-PHS*	NSF or those that have adopted	Research, Career, Fellowships, Training	9510	Addendum
Non-Federal*	Non-Profit For-Profit	Research, Gifts, Services, MTA, UCOP programs	700U	Addendum
Unfunded Projects Clinical Research	Internal unrestricted	Clinical Research	700U	Addendum

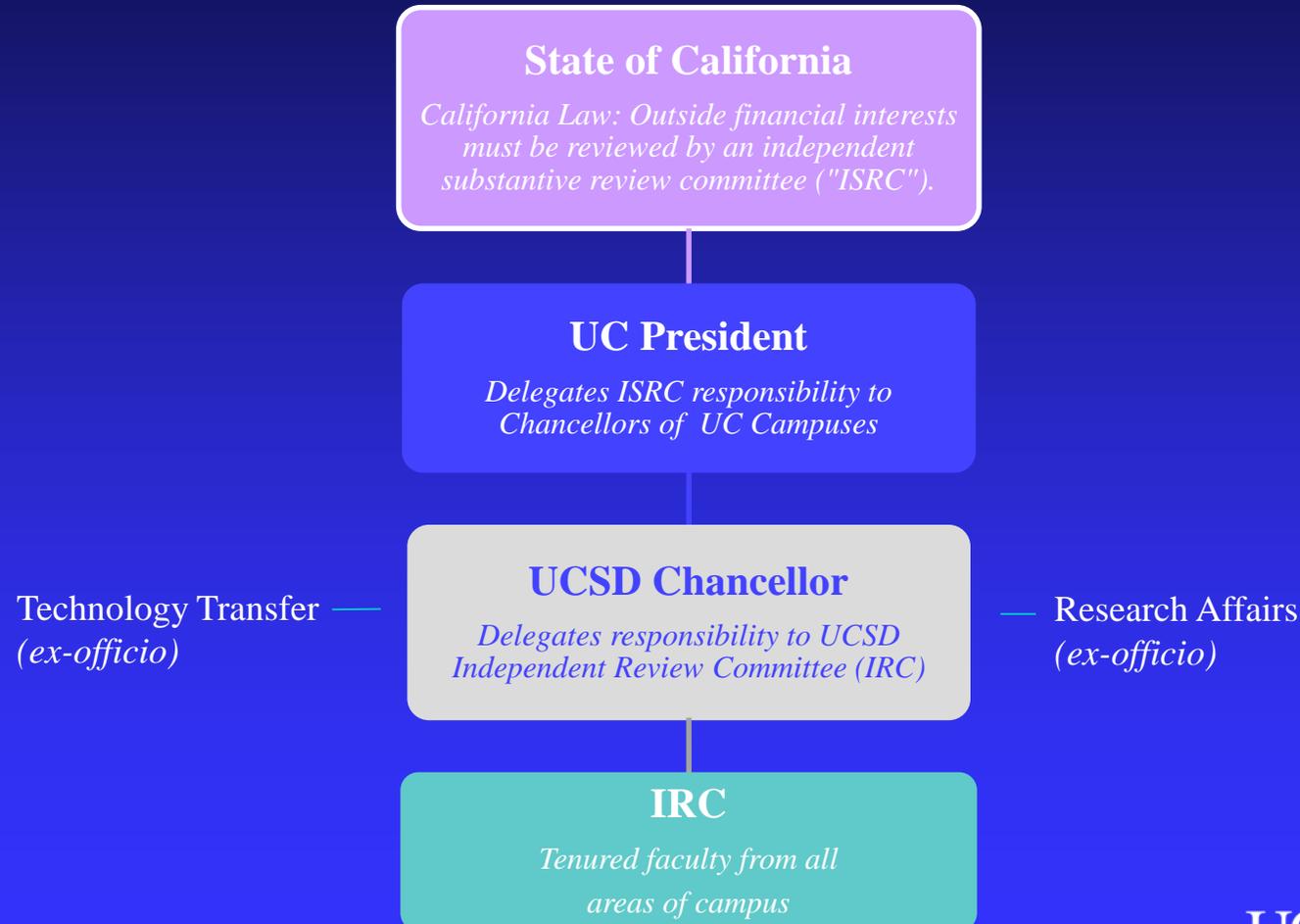
There are different COI financial disclosure thresholds and forms required for different sponsors

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

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

Independent Review Committee (IRC) on Conflict of Interest



Common IRC Management Strategies

- Reduction of the financial interest(s)
- Elimination of relationships that create actual or potential conflicts
 - For example, step down from the Board of Directors
- Disclosure of the financial interest(s) in presentations and publications of research results
- Disclosure of the financial interest(s) in the Informed Consent Form, if applicable
- Ensuring the protection of students and postdoctoral scholars by disclosure of interests or appointment of a co-advisor
- Discontinue consulting and any other recompensed activities during the course of a research project
- Monitoring of the project by the Conflict of Interest Management Subcommittee (COIMS)

COI Contact Information

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

Jennifer J. Ford, Director, jjford@ucsd.edu

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RESEARCH COMPLIANCE AND INTEGRITY

**Institutional Animal Care and Use
Committee (IACUC) Office**

Kristen Anderson-Vicino

Research Compliance and Integrity

Institutional Animal Care and Use Committee Office

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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

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

PI 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

PI 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

Congruency Verification

- NIH, NSF and most federal extramural funding agencies require verification that the IACUC has approved all proposed animal studies before they will fund grant proposals
 - Termed “congruency verification”
- OLAW defines congruence as “agreement between the animal activities described in a grant and the animal activities reviewed and approved by the IACUC”

Congruency Verification (continued)

- The Sponsored Project Offices (OCGA, HSSPPO and SIO) work directly with the IACUC Office to provide assurance to the funding agency of “congruence”
- IACUC Office compares grant proposal to approved animal use protocol (“side by side”) and provides feedback to the contracts and grants offices
- The contracts and grants offices provide the assurance to the funding agency
- Most of the time verification is not done until funding is imminent (JIT)

Congruency Verification (continued)

- Please educate your PIs that they should routinely amend their animal protocol to match any new or supplemental grant proposals
- If they do that early in the process, there should be no delays at funding time

Inter-Institutional Work

- Please educate your PIs that inter-institutional work using animals has very strict rules and they must carefully read the UCSD IACUC Inter-Institutional Policy at 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>

Inter-Institutional Work

Outgoing Subs

- Subcontracts to other institutions that include animal work must have an MOU or contract with specific language
- Any animal work being conducted at other institutions (where the funding is coming through UCSD) must also be verified as congruent
- A copy of the animal use protocol and IACUC approval letter from other institution(s) must be provided to the IACUC Office

Inter-Institutional Work

Incoming Subs

- Incoming subcontracted work does not require a congruency verification as the onus is on the prime institution to assure congruence
- An inter-institutional assurance is used for U.S. Institutions that receive PHS funding but do not have their own animal care and use program, facilities or IACUC
- Assures that the project will be conducted in compliance with PHS Policy and the PHS Assurance of the Assured Institution
- Inter-institutional agreements should be routed to the IACUC Office

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

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Export Control Office

Brittany Whiting

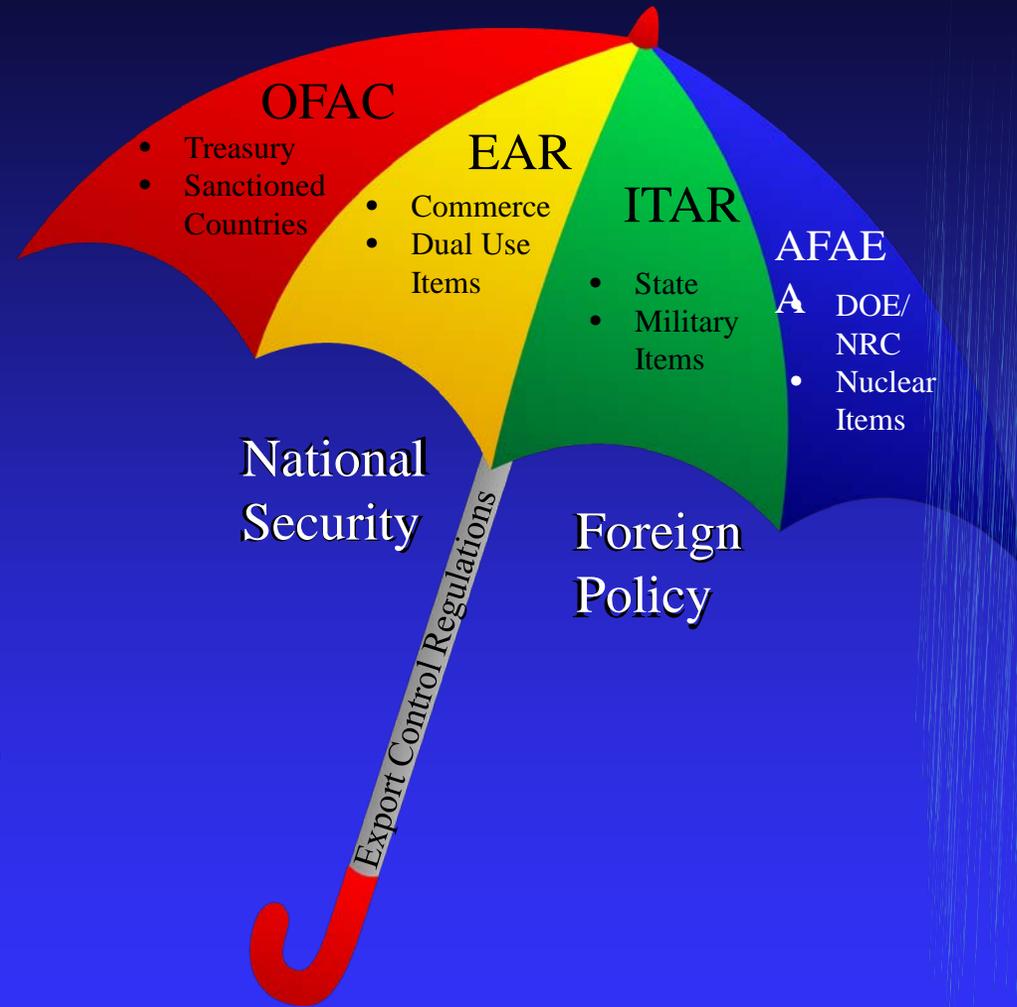
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Export Control Office

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So... what ARE Export Controls?



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

UC San Diego Export Control Office

- Identifies and manages export risks for U.S. national security & foreign policy to facilitate university research
- 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



Export Red Flag Reviews

People

- Restricted entities?
- Foreign person access to export restricted technology?

Places

- Controls are based on the country or national status of persons accessing or receiving export controlled items

Things

- Equipment, materials, software, technology

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



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**

THINGS: What is Export Restricted?

Equipment & Materials



Software



Technology or
Technical Data

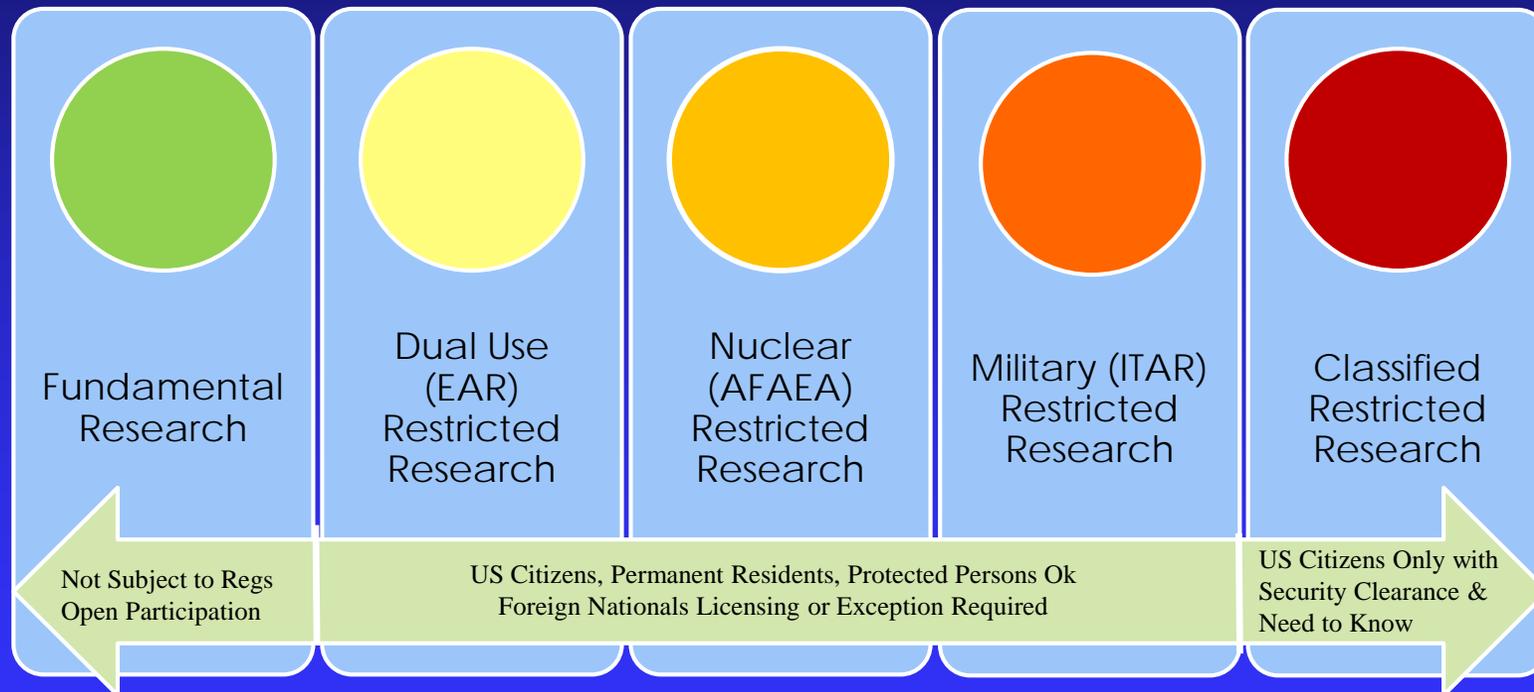


Prohibited End Uses



Nuclear both civil & weapons, chemical & biological weapons, rockets & UAVs

Spectrum of Research & Export Controls



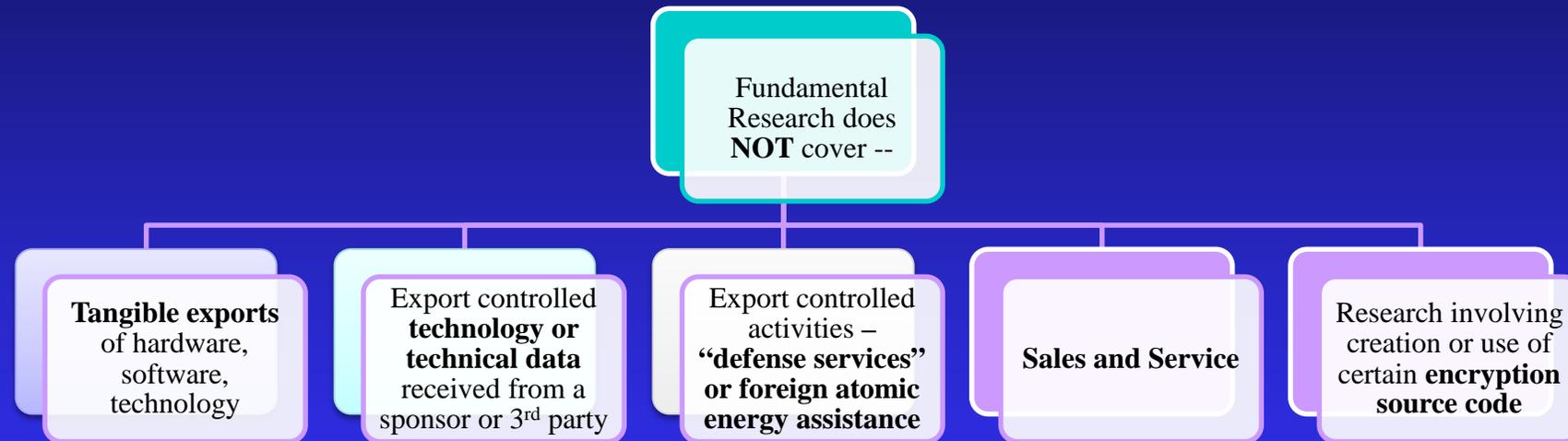
Key Exemptions to Export Controls

Public Domain
or Published
Information

Patented
Technology

Fundamental
Research

Limits of the Fundamental Research Exclusion



Transactions involving **sanctioned countries, individuals and entities and restricted end-uses** must be reviewed independent of fundamental research, for licensing requirements.

Export Control Videos on UC Learning

Topics:

University Research: 6 minutes, 45 seconds

Traveling Abroad: 4 minutes, 28 seconds

ITAR: 7 minutes, 40 seconds

International Shipping Overview

International Shipping Documentation

Biological Agents: 5 minutes, 4 seconds

OFAC: 3 minutes, 52 seconds

Who should watch them?

- Staff – use as part of new hire training, watch when you have a question
- Students, post-docs, researchers
- Faculty

<http://blink.ucsd.edu/sponsor/exportcontrol/training.html>

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Export Control Office Contact Information

- Export Control Office Website:
<http://blink.ucsd.edu/sponsor/exportcontrol/>
Email Questions: export@ucsd.edu
Telephone: (858) 534-4175

Brittany Whiting, Director

Garrett Eaton, Senior Export Analyst

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

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
McMahill

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

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Email: export@ucsd.edu

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