University of California 2019 Ethics, Compliance and Audit Symposium REACHING NEW HEIGHTS

Export Controls in Medical Research

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Learning Objectives

- Gain an understanding of export control regulations and their impact to medical research.
- Explore risks of export controls in medical research through case-study examples (including interactions with sanctioned countries).
- Discuss mitigation techniques and best practices for managing risk.



Introduction to St. Jude Children's Research Hospital

The mission of St. Jude Children's Research Hospital is to advance cures, and means of prevention, for pediatric catastrophic diseases through research and treatment. Consistent with the vision of our founder, Danny Thomas, no child is denied treatment based on race, religion or a family's ability to pay.

- St. Jude Department of Global Pediatric Medicine
- NIAID Centers of Excellence for Influenza Research and Surveillance



Activities of Concern

- International research collaborations / humanitarian aid
- International shipments
- Overseas travel
 - Issues can arise during scientific discussions or conferences
 - Destination may be sanctioned and require a license from OFAC (e.g., Cuba, Syria, N.Korea, Iran)
 - Medical devices that have not been approved or cleared in the U.S. must follow the export provisions of the Federal Food, Drug and Cosmetic (FD&C) Act; permit or certificate may be required.
 - Commercially available electronic devices may contain pre-loaded encryption software (such as, BitLocker, DUO)
- Provision of financial assistance or professional services
- Deemed exports
- Contract negotiations containing export control language



U.S. Department of Commerce, Bureau of Industry & Security (BIS) Administers the Export Administration Regulations (EAR) Items Controlled for Export are Defined in the Commerce Control List



U.S. Department of State, Directorate of Defense Trade Controls (DDTC) Administers the International Traffic in Arms Regulations (ITAR) Items Controlled for Export are Defined in the US Munitions List



U.S. Department of Treasury, Office of Foreign Assets Control (OFAC) Administers the Foreign Assets Control Regulations (FACR) and enforces the trade sanctions based on U.S. foreign policy and national security goals



What does it mean to "export"?



An actual shipment or transmission out of the U.S., including the sending or taking of an item out of the U.S. in any manner.



Releasing or otherwise transferring "technology" or source code to a foreign person in the U.S. (a "deemed export").



Performing a defense service on behalf of, or for the benefit of, a foreign person, whether in the United States or abroad.



Any release in the United States of "technical data" to a foreign person is deemed to be an export to **all** countries in which the foreign person has held or holds citizenship or holds permanent residency. (22 CFR §120.17)



Any release in the United States of "technology" or source code to a foreign person is a deemed export to the foreign person's *most recent* country of citizenship or permanent residency. (15 CFR §734.13(b))

Mitigation Step #1

Prior to shipping research equipment or materials out of the country, work with your Export Control Officer to determine whether an export license is required.

The CCL is a complex and lengthy document- are your PI's aware of it and if so would they *really* read it?







EAR: Classifications associated with Biological Agents, Toxins, and Genetic Elements

ECCN 1C351: Human and animal pathogens and "toxins"

ECCN 1C353: Genetic elements and genetically modified organisms

ECCN 1C991: Vaccines, immunotoxins, medical products, diagnostic and food testing kits

ECCN 1C354: Plant pathogens

ECCN 2B352: Equipment capable of use in handling biological materials

Technology: ECCNs 1E001, 1E351, 2E001, 2E002, 2E301

Are Export Controls all that important for a hospital?

- U.S. Department of Commerce Bureau of Industry and Security (BIS), Office of Export Enforcement (OEE)
 - Investigation conducted
 - Two occasions of exporting without a license
 - Animal pathogens (1C352)
- Warning Letter considered if future violations occur



UNITED STATES DEPARTMENT OF COMMERCE Bureau of Industry and Security WASHINGTON FIELD OFFICE Office of Export Enforcement 381 Elden Street, Suite 1125 Herndon, Virginia, 20170

In reply refer to Case Number

WARNING LETTER

Dear

The Bureau of Industry and Security (BIS), Office of Export Enforcement (OEE), is responsible for the enforcement of the Export Administration Act of 1979, as amended, 50 U.S.C. App. Sections 2401-2420 (2000) (the Act), and the Export Administration Regulations (EAR), 15 C.F.R. Parts 730-774 (2006) (the Regulations). OEE investigates violations of the Act and Regulations and pursues penalties, both criminal and administrative, that can result from violations of the Act and Regulations. Violations of the Regulations are set forth in Section 764.2 of the Regulations and the penalties are set forth in Section 764.3.

The Washington Field Office has completed an investigation of Hospital that involved the following matter:

		l exported				to
	on two occasions	without obtaining	the required	U.S. Department	of Comme	rce
license. On			A REAL PROPERTY	lexp	orted	to
the	21		1.000	g and the	1000	
EAR and lis	sted on the Commerc	ce Control List un	is a der Export Co	commodity that is emmodity Classific	subject to ation Num	the
	nimal pathogens					690
exports cons	titute a violation of 1	15 CFR § 764.2 (a)) - Engaging i	in prohibited condu	ct.	

We have reviewed the findings of this investigation and believe that the referenced conduct constitutes violations(s) of the Act and/or Regulations. However, based upon the facts and circumstances known to OEE at this time, OEE has decided not to refer this matter for criminal or administrative prosecution and is closing this matter with the issuance of this Warning Letter.

This Warning Letter will become part of the record and will be considered if future violations occur. OEE may reopen its investigation of this matter should additional evidence be received or if it appears that incorrect information was provided to OEE during the course of our investigation. If additional investigation is warranted, OEE may then pursue criminal prosecution and/or administrative sanctions.

Mitigation Step #2

- Global expansion increased the risk of an inadvertent interaction with a party who is in some way restricted from a business transaction. Where possible, incorporate procedures into business practices to screen potential business partners **before**:
 - Initiating foreign collaborations or agreements
 - Exchanging materials, data, confidential information, or money with foreign persons, academic institutions, governments, companies, or other foreign entities
 - Extending an invitation to a foreign national to visit or tour facilities



Situation

A PI wants to host a visitor from the Scientific Studies and Research Center of Syria. A review of the SSRC website reveals that the goal of SSRC is to promote scientific activities in Syria and develop the country in informatics. In anticipation of the visit, the PI wishes to export a piece of software to the visitor for review.

Should we be concerned?

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ASK YOURSELF

Are there any red flags with this transaction?

How well is the visitor known?

What are the results of the RPS?

Solution

A restricted party screen reveals that SSRC is listed as a restricted party on the Entity List and the SDN list.

The restricted party screen also reminds us that Syria is a sanctioned country.

This PI should seek guidance from his or her export contacts!

UC holds a systemwide unlimited license for screening.

Mitigation Step #3

- Protect fundamental research and remind the research community that information arising from fundamental research may be excluded from the export control regulations but that exclusion **does not** extend to the physical export of a controlled item.
 - "Fundamental research means research in science, engineering, or mathematics, the results of which ordinarily are published and shared broadly within the research community, and for which the researchers have not accepted restrictions for proprietary or national security reasons."

"Sure, I'll get that high path flu out to you next week. No need for a license since it is a product of fundamental research."

Fundamental Research

EAR (15 CFR 734.8(c))

- The research <u>is not</u> fundamental research if:
 - Sponsor <u>approval</u> is required prior to publication
 - Publication of the <u>results</u> of the project are restricted
 - Other access and dissemination restrictions are in the agreement, such as:
 - DFARS 252.204-7000
 - DFARS 252.204-7008 / 7012
 - Restricted to U.S. persons only





Mitigation Step #4

- Publish research results in a timely manner through one of the means that qualifies as "publicly available" or "in the public domain." Consult with your technology transfer or patent office if the data concerns a patentable invention.
- Do not accept restrictions on access to or dissemination of information



Scenario: A foreign student is working in the laboratory on a project to develop novel mechanisms for growing highly pathogenic avian influenza for the purpose of generating a new vaccine. Which of the following may present a deemed export issue?

- Variation 1: The projects is funded by Pharma who requires that the results remain unpublished for commercialization purposes.
- Variation 2: The project is NIH funded and the results are fully expected to be published and freely shared with the scientific community.
- Variation 3: The project is DOD funded and the grant restricts access to only US persons.

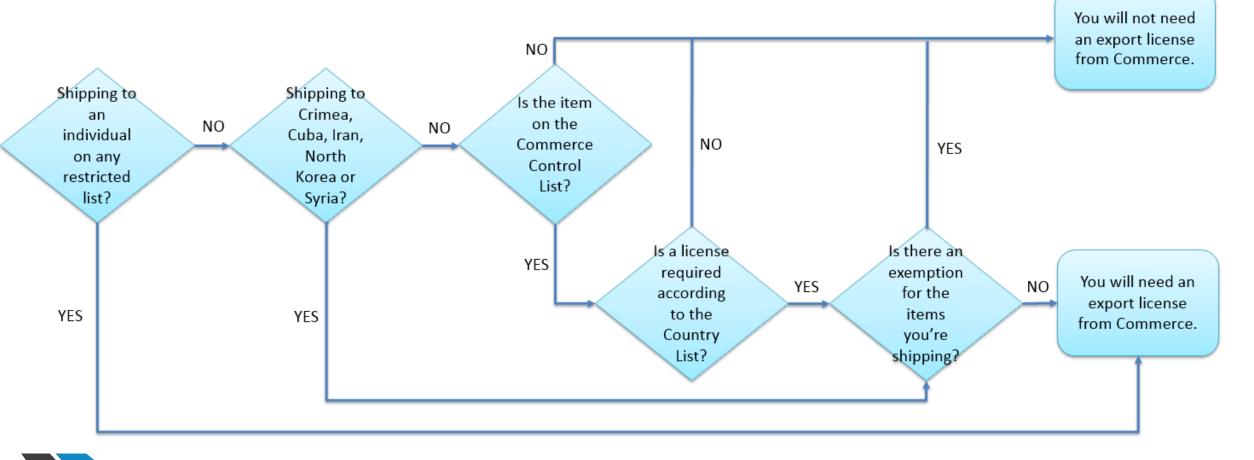


Be cognizant of Red Flags

- Unusual routing requests
- Unusual shipping requests
 - Request to export bacteria to another country as a letter
 - Request to modify an item so that it will pass more easily through checkpoints
 - Request for unusually large numbers of an item
 - Request to incorrectly value a shipment
- Requests to participate in unsanctioned boycotts
- Research involving travel to, shipments to, or collaboration with embargoed countries



Export License Decision Tree (Dept. of Commerce)



Foreign Assets Control **Regulations (FACR)**

- Cuban Assets Control Regulations (CACR): 31 CFR Part 515
- Iranian Transactions and Sanctions Regulations (ITSR): 31 CFR Part 560
- Syrian Sanctions Regulations (SSR): 31 CFR Part 542
- Ukraine-Related Sanctions Regulations (USR): 31 CFR Part 589



Sanctions Programs and Country

Information OFAC administers a number of different sanctions programs. The sanctions can be either comprehensive or selective, using the blocking of assets and trade restrictions to accomplish foreign policy and national security goals. Click here for information about an OFAC "Country List."

North Korea Sanctions

- Cuba Sanctions
- Iran Sanctions
- Ukraine-/Russia-related Sanctions
- Syria Sanctions
- Counter Terrorism Sanctions
- Counter Narcotics Sanctions Complete List of Sanctions Programs and Country.
- Information

https://www.treasury.gov/about/organizationalstructure/offices/Pages/Office-of-Foreign-Assets-Control.aspx

OFAC Sanction Programs: the very basics

- Each program has its own set of complex regulations.
- Sanctions programs are either:
 - Comprehensive: broad prohibitions on all transactions occurring within the named country, or
 - Selective: prohibitions are directed against named individuals or entities within the named country.
- Because each program is based on different foreign policy and national security goals, prohibitions vary requiring each activity to be reviewed on a case-by-case basis.
- Common areas impacted by OFAC sanctions:
 - Transfer of money or items to and from the sanctioned country
 - Travel to and from the sanctioned country
 - Collaborations involving the sanctioned country





Interactions involving OFAC sanctions require licensure.

- Interactions with a sanctioned entity require either a general or specific license.
- General License: 'blanket license' that broadly authorizes the performance of certain categories of prohibited activities
 - Requires that specific terms and conditions can be met and documented
 - Does not require the submission of a license application through OFAC **but**
 - You <u>must</u> keep records for 5 years that documents your activity complied with the general license,
 - You should work with your Export Control Officer to verify a general license is applicable and determine what documentation is sufficient
- Specific License: a written authorization issued on a case-by-case basis to a particular person authorizing a particular transaction
 - Requires an application be submitted through OFAC
 - Specific licenses should be requested as early as possible (approval times take months)
 - Work with the Export Control Officer on any license application





General License: Professional Meeting in Cuba

- Travel to attend a professional meeting or conference in Cuba is permitted under a general license provided that:
 - The purpose of the meeting or conference directly relates to the traveler's profession, professional background, or area of expertise, including area of graduate-level full-time study;
 - The traveler's schedule of activities does not include free time or recreation in excess of that consistent with a full-time schedule of attendance at, or organization of, professional meetings or conferences.
- Each person relying on the general license must retain specific records related to the travel.
- Example: A physician whose academic profession is cancer research may attend a professional meeting on cancer immunotherapy in Cuba under this general license. If the same physician has an interest in literature, he or she can not attend a literature and culture conference in Cuba without a specific license issued by OFAC.



Specific License: Attending and Speaking at a Conference in Iran

 Travel to Iran is generally permissible. However, no general license exists for attending a professional meeting.

 Currently, the attendance at a professional meeting is a prohibited activity under the Iranian Sanctions Regulations and a specific license from OFAC is required.



Mitigation Step #5

• Consider all of the potential interactions that might occur between your investigators and clinicians and a sanctioned country.



Medical Referral and Consultation Services under the FACR

- Cuba (31 CFR 515.575(a): Authorizes US persons to engage in transactions that are related to humanitarian projects in or related to Cuba that are designed to <u>directly benefit</u> the Cuban people, including "medical and healthrelated projects."
- Syria (31 CFR 542.516(a): Authorizes non-governmental organizations to export or re-export services to Syria in support of certain not-for-profit activities, including activities to support humanitarian projects to meet basic human needs in Syria, including the provision of health services.
- Iran (31 CFR 560.545(b)(1): Authorizes OFAC to issue specific licenses on a case-by-case basis for "US persons to engage in"... "[t]he provision of donated professional medical services."

Assistance to Obtain Visa for Entry into the United States for Treatment

- If a physician determines that a patient residing in a foreign country is eligible and accepts him/her for treatment, the patient's family is responsible for obtaining the appropriate visa for entry into the U.S.
 - Considered "personal communication" and not prohibited by OFAC; meets the definition of "informational materials"
- To support the U.S. visa application, the institution typically provides written verification to the patient's family that the patient would be treated at the hospital.
- Upon lawful entry into the U.S., the hospital generally pays for the transactions incident to the activities (i.e., medical care) for the visas that were issued.



Protocol Adjustments and Medical Treatment in Patient's Home Country

Provision available in the CACR and SSR.

- 31 CFR 515.575(a)
- 31 CFR 542.516(a)
- ITSR 31 CFR 560.545(b)(1): reviewed on case-by-case basis
- When in doubt err on the side of caution and work with your Export Control Officer to seek an advisory opinion (or apply for license)



Licenses Currently Held

- **Iran**: License provided to
 - Engage in all transactions necessary to provide free medical consulting services, clinical protocol consults, and manuscript and grant application reviews to persons ordinarily resident in Iran; and
 - Engage in all transactions necessary to provide medical treatment to children who are ordinarily resident in Iran at St. Jude facilities in the U.S.
 - Serve as a PhD advisor to a student in Iran
 - Conduct an education workshop in Iran
 - Offer technical support to Cure4Kids

• Syria & Cuba: activities fall within the scope of transactions or exempt





Case Example: Dr. Thomas Butler

- 2003 Chief of Infectious Diseases, Texas Tech
- 2003-reported to the FBI that 30 vials of Yersinia pestis were missing and presumed stolen
- Found Guilty of:
 - Making false, fraudulent and fictious statements regarding the exports to federal agents
 - Making an unauthorized export to Tanzania
- Two years in prison. Surrendered medical license
- Paid \$37,400 civil penalty
- 10 years denied export privileges

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Case Study: Dr. Mohamed Nazemzadeh

- Associations with University of Michigan and Henry Ford Hospital
- Develops MRI systems / applications to assist physicians performing surgery on epilepsy patients and brain cancer
- Desires to share his MRI expertise with native country
- Sought to purchase refurbished MRI coils for export to his home country via The Netherlands

Export Control Considerations:

- Is the MRI coil export controlled?
- What country and to whom is it going (Sanctions / Restricted Parties)?





Case Study (continued): Dr. Nazemzadeh

- 2011: corresponded via email with a US-based MRI supplier
 - Intent to purchase and export to Iran
 - Supplier reported the inquiry to US Department of Homeland Security
- Undercover operation ensued; Allegedly knew of the sanctions
- Arrested in 2012
- Charges dropped in 2016
- "I'm not saying medical equipment shouldn't go to Iran, but it should go there lawfully." – Feve, Assistant US Attorney

Mitigation # 6 Leverage your Experts! Export Control Contacts

- UC Berkeley; Alaisha M. Hellman
- UC Davis; Craig Allison
- UC Irvine; Amy Green
- UCLA; Ann Pham
- UC Merced; Deborah Motton
- UC Riverside; Charles Greer
- UC San Diego; Brittany Whiting

- UC San Francisco; Joan Doherty
- UC Santa Barbara; Brian McCurdy
- UC Santa Cruz; Lisa Coscarelli
- ANR; Kathleen Nolan
- Lawrence Berkeley National Laboratory; Shilpani Perera
- UC Office of the President; Marci Copeland

https://www.ucop.edu/ethics-compliance-audit-services/compliance/international-compliance/campus-contacts.html