

Export Controls in Medical Research: Compliance Considerations for International Collaborations

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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

- ▶ 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
- ▶ St. Jude Global
- ▶ WHO Collaborating Centre for Childhood Cancer
- ▶ NIAID Centers of Excellence for Influenza Research and Surveillance

Case Example: Warning Letter

- ▶ 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
3811 Eden Street, Suite 1125
Herndon, Virginia, 20170

In reply refer to Case Number [REDACTED]

WARNING LETTER

Dear [REDACTED]:

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 [REDACTED] Hospital that involved the following matter:

[REDACTED] I exported [REDACTED] to [REDACTED] on two occasions without obtaining the required U.S. Department of Commerce license. On [REDACTED] I exported [REDACTED] to [REDACTED] and the [REDACTED] is a commodity that is subject to the EAR and listed on the Commerce Control List under Export Commodity Classification Number 1C352 - Animal pathogens. These exports constitute a violation of 15 CFR § 764.2 (a) - Engaging in prohibited conduct.

We have reviewed the findings of this investigation and believe that the referenced conduct constitutes violation(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 [REDACTED] 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.

Export Control Basics



U.S. Department of Commerce, Bureau of Industry & Security (BIS)
Administers the Export Administration Regulations (EAR)



U.S. Department of State, Directorate of Defense Trade Controls (DDTC)
Administers the International Traffic in Arms Regulations (ITAR)



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))

What is “technical data” and “technology”?

- ▶ Under the ITAR: “Technical data” is information required for the design, development, production, manufacture, assembly, operation, repair, testing, maintenance or modification of defense articles.
- ▶ The information can be in the form of: blueprints, drawings, models, photographs, plans, instructions, formulae, and documentation.
- ▶ It includes software related to a defense article.
- ▶ Under the EAR: “Technology” includes information necessary for the “development,” “production,” or “use” of a product.
- ▶ The information can be include: Designs, drawings, and blueprints; test procedures and results; product configuration and interface information; production and manufacturing plans or instructions.

What is a “defense service”?



Furnishing assistance (including training) to foreign persons (in the U.S. or abroad) in the design, development, engineering, manufacture, production, assembly, testing, repair, maintenance, modification, operation, demilitarization, destruction, processing, or use of defense articles.



Furnishing any controlled technical data (in the U.S. or abroad) to foreign persons.



Military training.



Fundamental Research

EAR (15 CFR 734.8(c))

- ▶ “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.

ITAR (22 CFR 120.11(a)(8))

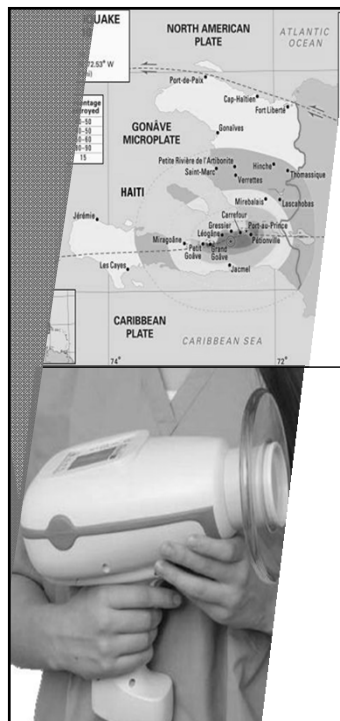
- ▶ “Through fundamental research in science and engineering at accredited institutions of higher learning in the U.S. where the resulting information is ordinarily published and shared broadly in the scientific community.”

The research is not fundamental research if:

- Sponsor approval is required prior to publication
- Publication of the results 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

Activities of Concern

- ▶ International research collaborations / humanitarian aid
- ▶ International shipments of certain viruses, equipment, software, or technology
- ▶ Overseas travel
 - Issues can arise during scientific discussions or conferences
 - Destination may be sanctioned and require a license from OFAC (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 export
- ▶ Contract negotiations containing export control language



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

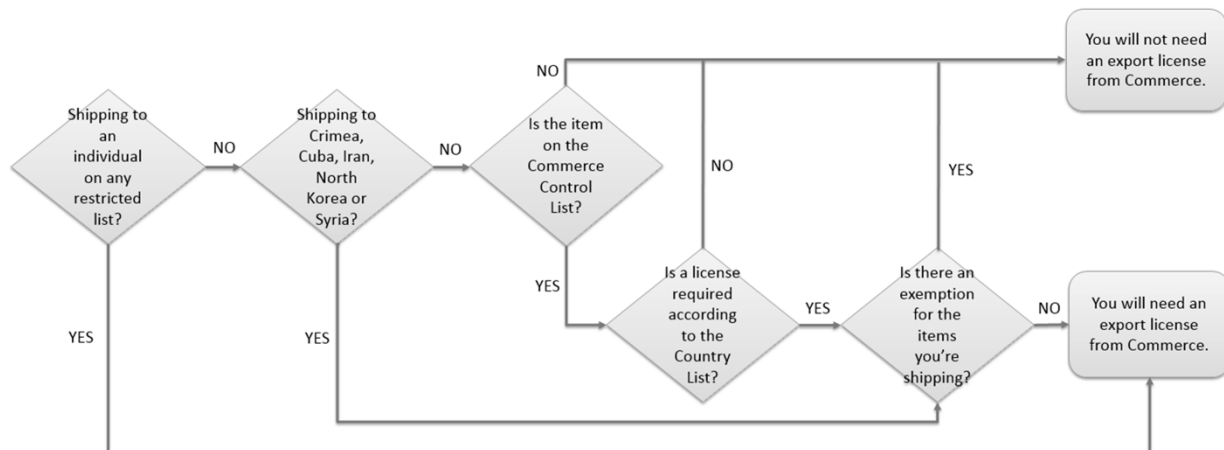
ECCN 1C991: Vaccines, immunotoxins, medical products, diagnostic and food testing kits

ECCN 1C354: Plant pathogens

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

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

Export License Decision Tree (Dept. of Commerce)



Items on the CCL are Controlled to Specific Countries

- Example: Highly Pathogenic Avian Influenza is controlled for 'CB1' reasons

Commerce Country Chart																
Countries	Reason for Control															
	Chemical & Biological Weapons			Nuclear Nonproliferation		National Security		Missile Tech	Regional Stability		Firearms Convention	Crime Control			Anti-Terrorism	
	CB 1	CB 2	CB 3	NP 1	NP 2	NS 1	NS 2	MT 1	RS 1	RS 2	FC 1	CC 1	CC 2	CC 3	AT 1	AT 2
Afghanistan	X	X	X	X		X	X	X	X	X		X		X		
Albania ^{2,3}	X	X		X		X	X	X	X	X						
Algeria	X	X		X		X	X	X	X	X		X		X		

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 project 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.
- Consideration: HPAI is export controlled to all countries.

Other Considerations

► Exporting

- Fundamental Research Exclusion does not apply to the physical export of items. A license from Commerce would be required to export a controlled item if some other exception were not available.

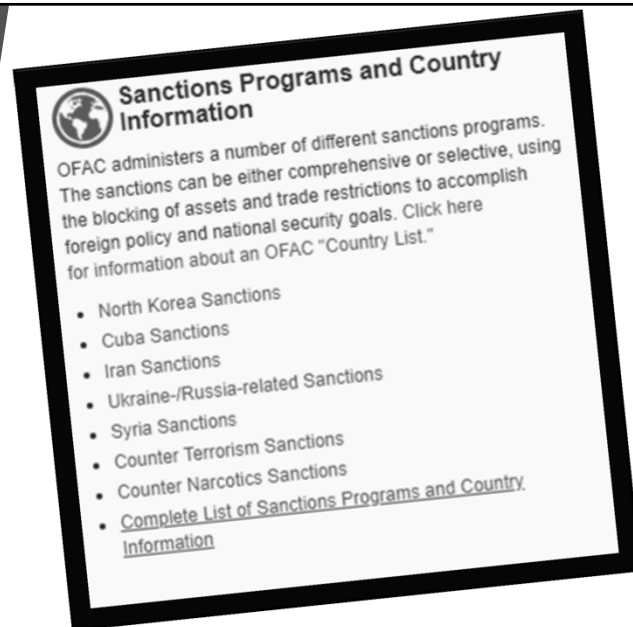


► Importing

- Many countries prohibit the importation of plants, animal products, pharmaceuticals, etc.
- Additional certifications that may be needed
- Customs duties / fees
- Licensed Customs Broker

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



<https://www.treasury.gov/about/organizational-structure/offices/Pages/Office-of-Foreign-Assets-Control.aspx>

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 directly benefit the Cuban people, including “medical and health-related 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 - seek an advisory opinion (or apply for license) from OFAC

OFAC Licenses Obtained

- ▶ Iran: License provided to
 - (a) 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
 - (b) 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.
- ▶ Syria & Cuba: activities fall within the scope of transactions or exempt

Penalties

- ▶ Potential harm to national security and foreign policy interests.
- ▶ Negative impact on company / university, including reputation.
- ▶ Significant civil and / or criminal fines.
- ▶ Investigation costs.
- ▶ Debarment.
- ▶ Incarceration.
- ▶ Costs to fix mistakes / directed special compliance.

EAR	ITAR	OFAC
<ul style="list-style-type: none"> • Criminal: \$50k to \$1m or 5x the value of the export, whichever is greater, <u>per violation</u>; 10 years imprisonment. • Civil: \$10k-\$120k <u>per violation</u>; revocation of export privileges. 	<ul style="list-style-type: none"> • Criminal: up to \$1m <u>per violation</u> and 10 years imprisonment. • Civil: up to \$500k <u>per violation</u>; seizure and forfeiture of article; revocation of export privileges. 	<ul style="list-style-type: none"> • Criminal: \$50k-\$10m <u>per violation</u> and 10-30 years imprisonment. • Civil: \$11k-\$1m <u>per violation</u>.

Penalties (continued)



Monetary Fines

University of Massachusetts-Lowell fined \$100k

- Exported "EAR99" items to an organization that was on a denied parties list
- Fine suspended during probation period



Imprisonment

Dr. Nazemzadeh (University of Michigan, Radiation Oncology and Henry Ford Hospital)

- Export of "EAR99" medical device to Iran



Loss of exporting privileges



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 fictitious 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

Case Study: Dr. Mohamed Nazemzadeh



- ▶ Associations with University of Michigan and Henry Ford Hospital (Radiation Oncology)
- ▶ 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?
- Sanctioned vs non-sanctioned country
- Restricted Party / Prohibited Party

Case Study (continued): Dr. Nazemzadeh

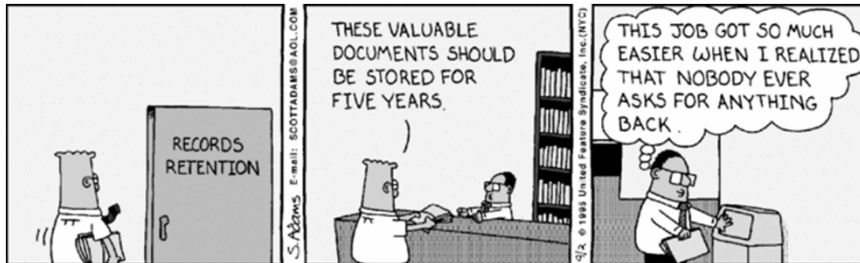
- ▶ 2011: corresponded via email with a US-based MRI supplier
 - Intent to purchase and export to Iran
 - Supplier reported the inquiry to US Department of Homeland Security
- ▶ Undercover operation ensued; Allegedly knew of the sanctions
- ▶ Arrested in 2012
- ▶ Charges dropped in 2016
- ▶ *"I'm not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

Mitigation Best Practices

- ▶ Network:
 - Get a seat at the table
 - Create a Committee / Working Group
 - Schedule one-on-one's and raise awareness
- ▶ Utilize external resources for outreach
- ▶ Review all the fine details in an agreement; ask questions to clarify understanding
- ▶ Audit / Monitor your export compliance system



Mitigation Best Practices (continued)



► Document! Document! Document!

- Reliable document management process
- 15 CFR 30.10; 22 CFR 123.22: Retention period
- 15 CFR 762.2; 22 CFR 122.5: Records to be retained

Mitigation Best Practices: 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
- Research involving travel to, shipments to, or collaboration with embargoed countries

Mitigation Best Practices: Boycotts



- ▶ Request to participate in an unsanctioned boycott
- ▶ Export Controls prohibit US persons from complying with certain requirements of unsanctioned foreign boycotts
 - Agreements to refuse or actual refusal to do business with boycotted countries
 - Agreements to furnish or actual furnishings of information about business relationships with boycotted countries

Questions?



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