

Export Controls in a Global Health Arena

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Session Topics

- Physical exports of specimens and equipment
- Exports of technical data
 - Deemed Exports
 - Exempt from export control laws
 - Fundamental Research Exclusion
- Sanctioned countries
- Restricted Party Screening
- Foreign Corrupt Practices Act
- Anti-Boycott Regulations
- How our institutions address export control issues

Prominent Export Control Regimes

- ITAR – “International Traffic in Arms Regulations”
- EAR – “Export Administration Regulations”
- OFAC (country specific sanctions) – “Office of Foreign Assets Controls”
- FDA – “Food and Drug Administration”

ITAR and Global Health

- *ITAR* = International Traffic in Arms Regulations
 - Covers products that were specifically designed, manufactured, or modified for military or space applications
 - Covers all agents and substances specifically designed, adapted, or modified for the purpose of harming humans, animals, or crops, including any medical countermeasures for protection from these agents or substances
- Very unlikely that Global Health projects would involve ITAR products or its associated technical data but possible
- Products or technical data may reference ITAR or export controls in its “legalese” language

ITAR and Global Health

- ITAR products and its associated technical data cannot be exposed (visually or orally) to foreign nationals without an export license
- Supporting a foreign government's military or space programs will probably require US government approval (*defense service*)
- Examples of ITAR or defense services in the medical profession:
 - Use of a FLIR thermal imaging camera to detect acute compartment syndrome of the leg in trauma patients
 - Assisting a foreign Navy with decompression illness aversion
 - Developing atropine injections designed to counter nerve agent poisoning

EAR and Global Health (Physical Shipments)

- Biological Agents (Human and Animal pathogens) and Toxins that are export controlled
 - Includes
 - All U.S. Select Agents (CDC/APHIS)
 - All viruses, bacteria, and “toxins” listed by the **Australia Group**, for example:
 - Dengue Virus
 - Bartonella quintana (Rochalimea quintana, Rickettsia quintana)
 - Shiga toxins (shiga-like toxins, verotoxins, and verocytotoxins)
 - Fungi: Coccidioides immitis or posadasii
 - Additional Considerations
- Controlled “genetic elements” and “genetically modified organisms”
- Vaccines against export controlled biological agents
- Immunotoxins, medical products, and diagnostic and food testing kits containing controlled toxins or subunits of toxins

EAR and Global Health (Physical Shipments)

- Exports of INDs are subject to US Food and Drug Administration requirements as described in 21 CFR §312.110(b). INDs may be exported when:
 - An IND is in effect for the drug under § 312.40, the drug complies with the laws of the country to which it is being exported, and each person who receives the drug is an investigator in a study submitted to and allowed to proceed under the IND; or
 - The drug has valid marketing authorization in Australia, Canada, Israel, Japan, New Zealand, Switzerland, South Africa, or in any country in the European Union or the European Economic Area, and complies with the laws of the country to which it is being exported, and complies with section 802(b)(1)(A), (f), and (g) of the act, and § 1.101 of this chapter; or
 - The drug is being exported to Australia, Canada, Israel, Japan, New Zealand, Switzerland, South Africa, or to any country in the European Union or the European Economic Area, and complies with the laws of the country to which it is being exported, the applicable provisions of section 802(c), (f), and (g) of the act, and § 1.101 of this chapter; or
 - Following stringent prior written certification/notification and ongoing documentation requirements are met; or
 - In the event of a national emergency in a foreign country, where the national emergency necessitates exportation of an investigational new drug with certain requirements fulfilled
- FDA controls are independent of EAR controls - both may apply to some INDs

EAR and Global Health (Physical Shipments)

- Most medical equipment used for medical treatment or the practice of medicine is only export controlled to comprehensively sanctioned countries (Cuba, Iran, North Korea, Sudan, and Syria) and some listed entities
 - Does not include items associated with nuclear proliferation or chemical/biological weapons
 - **Does not include equipment used solely for “medical research”**
- Donations of surplus material
 - Most clinical care products and devices do not require an export license unless sent to a sanctioned country (limited exception for Iran)

EAR and Global Health (Physical Shipments)

- Laptops and Computing Equipment
 - Standard off-the-shelf laptops and computers will not require an export license whether shipped or hand-carried
 - Technical data contained on the laptop may still be export controlled
 - High-tech or specialized computing equipment should be reviewed (e.g., customized processing capabilities)
- Software
 - Software associated with export controlled items will likely be export controlled
 - Source Code is export controlled, Object Code usually is not
- Encryption Products
 - Generally not export controlled if:
 - Available for purchase by the public, without restriction, from stock at retail selling points
 - Cannot be easily changed by the user
 - Designed for installation without further substantial support of the supplier
 - Encryption capability is ancillary to the primary purpose/function of the software
 - High level encryption is typically subject to control

Global Health and Export Controlled Technical Information

- Technical Information Exports
 - If an item requires an export license to be sent overseas, an export license will likely be required for any technical information associated with that item
 - For ITAR items: “technical data” associated with an item is controlled
 - For EAR items: “technology” associated with an item is controlled
 - May be controlled at a different level than associated item
 - Development, Production, and Use technology may have different levels of control
- Publicly available technical information is not subject to export control (unless provided as a defense service)

Global Health and Export Controlled Technical Data

- Deemed Exports
 - Export without crossing borders
 - Transfer of a controlled item or controlled information is "deemed" to be an export to the home country or countries of the foreign person

Technical Data Exempt from Export Controls

- Technical data NOT subject to export control laws:
 - Public Domain/Published Information
 - Educational Information Exclusion
 - When a specific exemption or general license is available
 - HIPAA data - Protected health information ≠ export controlled information
 - May have similar security requirements but HIPAA is not a factor in export reviews
 - “Fundamental Research” Exclusion

Fundamental Research Exclusion (FRE)

- Fundamental Research:
 - Basic/applied research that is ordinarily **published and shared broadly** within the scientific community
 - Pre-publication review OK
 - For US Government research, no restrictions on pre-publication dissemination or on participation by non-U.S. citizens
 - **Not subject to the EAR or ITAR**

Dual Use Research of Concern

- How the fundamental research exclusion can be lost quickly
 - “... research that is ordinarily **published and shared broadly** within the scientific community...”
- H5N1 example
- How our institutions handle DURC



Controls or Sanctions May Still Apply to FRE

Fundamental Research Exclusion (FRE) does not cover:

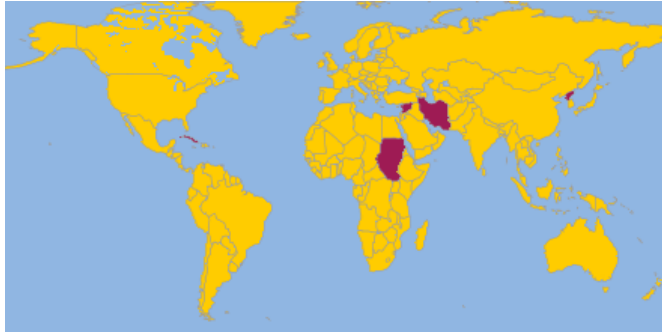
- Exports of “tangible” goods – (only applies to data and information)
- Activities/transactions that are not research
- Research performed overseas
- Research involving the use of export restricted information obtained from external sources

We still must check for:

- Country sanctions
- Restricted parties

Sanctions and Embargos

Office of Foreign Assets Controls
(OFAC)



- **CUBA**
- **IRAN**
- **NORTH KOREA**
- **SUDAN**
- **SYRIA**



Other countries with
sanction programs:



- Belarus
- Burma (Myanmar)
- Cote d'Ivoire (Ivory Coast)
- Congo

- Liberia
- Libya
- Somalia
- Zimbabwe

Sanctions

- OFAC sanctions cover financial transactions, shipments, travel, collaboration, etc.
- Each regulation for each country is different
- Examples: Regulations may authorize
 - Visitors to a U.S. campus on an F-1, J-1, H1B or certain other visas (but not a business visa)
 - Technology disclosures in limited instances
 - Activities related to publication or training (but perhaps not collaboration to create the publication or training)
- Regulations may include general licenses, meaning we do not need to get specific authorization for activities that are covered by the license
 - Sudan example

Sanctions

- Conferences
- Research
 - Transactions necessary and ordinarily incident to publishing
 - Travel
 - Services
- Physical shipments
 - Some exemptions/authorizations are available in the country-specific sanction or EAR
 - Information and informational materials
 - Items sent for humanitarian/medical relief
 - Personal communications equipment/software/service
 - Baggage for personal use
 - Must be EAR99 (list or CJ'ed) or specifically allowed
 - Country specific controls – it's absolutely necessary to evaluate specific scenarios against the applicable regulation

Restricted Party Screening

- U.S. Departments of State, Commerce and Treasury maintain lists of persons (individuals and entities) denied export privileges and/or barred from financial and other transactions for reasons related to U.S. security, foreign policy, or economics
- Access to the consolidated lists
 - <http://www.treasury.gov/resource-center/sanctions/SDN-List/Pages/default.aspx>
 - http://2016.export.gov/ecr/eg_main_023148.asp
 - <http://developer.trade.gov/consolidated-screening-list.html>

Restricted Party Screening

- Key step in every export review process
 - International collaborators (sponsors, key persons, subrecipients, consultants, and performance sites);
 - Foreign national employees/volunteers/students;
 - Foreign national visitors on campus; and
 - Other parties to any export.
- Screening for restricted parties may result in a “hit”
 - We must document that the restricted party is NOT the party we are screening (eliminate false hits)
 - True hits must be reviewed to determine licensing requirements and impact
 - Liable for compliance on the day of export
- Many academic institutions use commercial online service providers (e.g., Visual Compliance (eCustoms) or Amber Road)
 - Usually in more than one department

Foreign Corrupt Practices Act

**When working
with foreign
government
officials,**



“Government officials” may include:

- Foreign government employees and politicians
- Public international organizations (e.g. the World Bank, World Health Organization)
- Employees of foreign state owned or affiliated entities, including:
 - Doctors in state owned or operated hospitals
 - Professors in public universities
 - Purchasing agents at state owned entities
 - Family members of the above individuals

**it is illegal to
provide
“anything of
value”**



“Anything of value” may include:

- Cash or services
- Lavish gifts
- Kickbacks
- Loans
- Charitable contributions
- Scholarships or Admissions
- Excessive entertainment expenses
- Title of honor

**in order to
obtain an unfair
advantage**



“Unfair advantage” may include:

- Influencing an official act or decision
- Obtaining or retaining business or funding
- Portraying “competitors” poorly
- Ensuring the lack of prosecution for illegal activity
- Securing special tax or customs treatment

Foreign Corrupt Practices Act

- Due diligence in risk assessment for unfamiliar organizations (history, activities, reputation)
- Document ANY payment to a government official including specification of goods/services provided, invoicing, and payment.
 - Confirms a bona fide transaction
- Tribal gifts and similar customs: this is a custom, not a bribe as long as no unfair advantage is gained
- Red flags
 - Cash transactions
 - Requests for false invoices or other documents
 - Working with government officials, individuals, family members, or entities with close ties to or recommended by government officials

Anti-boycott Compliance

- <https://www.bis.doc.gov/index.php/enforcement/oac>
- Laws require U.S. organizations to refuse to participate in foreign boycotts that the U.S. does not sanction
- Prohibited conduct includes:
 - Agreements to refuse or actual refusal to do business with or in Israel or with blacklisted companies.
 - Agreements to discriminate or actual discrimination against other persons based on race, religion, sex, national origin or nationality.
 - Agreements to furnish or actual furnishing of information about business relationships with or in Israel or with blacklisted companies.
 - Agreements to furnish or actual furnishing of information about the race, religion, sex, or national origin of another person.
- U.S. persons must report requests to take certain actions to comply with, further, or support an unsanctioned foreign boycott (even if there was no agreement or action)

Anti-boycott Compliance

- Treasury Department publishes a list of countries that cooperate with the Arab Boycott of Israel. As of March 30, 2017, that list includes:
 - Iraq
 - Kuwait
 - Lebanon
 - Libya
 - Qatar
 - Saudi Arabia
 - Syria
 - United Arab Emirates
 - Yemen



Export Controls and Setting Up a Field Office Overseas

- Office Equipment and Supplies – may be cheaper to procure from the United States but consider:
 - Foreign countries import duties
 - Manufacturer Support
 - Electricity/Voltage Differences
- Hiring of Foreign Nationals
 - All export control laws still apply, including Deemed Export rules
 - Involve international attorneys for payment of income taxes
- Traveling with Cash
 - All countries have limits on the amount of cash and cash equivalents that may be taken into or out of a country

Export Controls at UMB

- Fundamental Research institution – we do not accept any classified research or publication restrictions
- Risk profile:
 - Professional campus (medical, dental, nursing, pharmacy, social work, law)
 - Many foreign national employees/visitors on campus
 - Export concerns spring primarily from country sanctions
- Export control team: 3 people with export compliance duties, from Sponsored Programs Administration; Environmental Health & Safety; University Counsel

Export Controls at UW

- Tries to maintain the Fundamental Research Exclusion but will accept controlled research as an exception
- Sensitive to data and materials coming in from an outside party as it may still be export controlled
- Risk Profile similar to UMB and UV
 - Large Medical School
 - Large percentage of foreign nationals
 - Actively pursuing a global environment
- Export Control Team: Evolving. Hired to oversee export compliance across the university; Existing Secure Research Officer and a Facility Security Officer for controlled research

Export Controls at UVA

- Accepts publication restrictions and other types of controlled research
- Risk profile:
 - Professional campus (medical, nursing, and law)
 - Many foreign national employees/visitors on campus
 - Export concerns related to research
 - country sanctions,
 - use of ITAR-controlled equipment to perform fundamental research, and
 - background controlled information needed for development research
- Export control team: 2 FTE for export/sanction plus me
- Collaborating/Coordinating Offices: Sponsored Programs; Environmental Health & Safety; University Counsel; Human Resources; Procurement; University Compliance; Financial Operations; Vice President for Research; and Provost (International Studies).

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