



Managing Export Control Compliance in Biomedical Research

presented by

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> Breakout Session R501: Agenda

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1. What Are Export Controls?
 2. Export Compliance Risks Specific to Biomedical Research
 3. Increased U.S. Government Enforcement Efforts
 4. Research-based Exclusions from Certain Control Requirements
 5. Practical Tools to Minimize Individual and Institutional Risk
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1. What Are Export Controls?

Regulatory Overview

Regulations (Department of Commerce, Defense, State and Treasury) controlling what hardware, software, technology/technical data can be:

- Exposed to certain foreign nationals working/residing in the U.S.
- Shipped/transported/transmitted by any means to certain destinations for certain end uses by certain persons/entities

Enforcing Agencies

- Export Administration Regulations (EAR) –Dual Use controls
- International Traffic in Arms Regulations (ITAR) –Defense controls
- Office of Foreign Assets Controls (OFAC) –Embargoed country transaction controls

Key Objectives

- Protecting national security
- Countering nuclear proliferation and *bioterrorism*
- Monitoring missile technology
- Promoting regional stability

What Constitutes an “Export” of Hardware, Software, Technology/Technical Data?

Shipment/transmission of such items by any means:

- Cargo shipment, electronic data transmission, courier-shipment, hand-carried

Deemed Export Concept:

- Visual and computer access to export controlled technology or data, occurring in the U.S. by foreign persons of certain countries validly on temporary student or employment visas, neither U.S. citizens nor Permanent Residents (export is “deemed” to occur upon foreign national’s return to home country); or release to foreign nationals abroad.
- Definition of “foreign persons” includes companies not incorporated in the U.S., foreign governments, and international organizations.
- ITAR incorporates analogous concept for purposes of defense articles and services, but subject to ITAR country prohibitions

> 1. WHAT ARE EXPORT CONTROLS?

Types of Controls

EAR-Commerce Department “Dual use” controls (15 CFR 700-799):

- Commodity/hardware, software, technical data with both civilian and potential military or nuclear proliferation capabilities.
- Technical data/technology: blueprints, plans, diagrams, models, formulae, tables, engineering designs, and specifications, manuals and instructions written or recorded on other media or devices such as disk, tape read-only memories.

ITAR- State Department controls (22 CFR 120-130):

Defense Article:

- Hardware, software and technical data specifically designed, developed, configured, adapted or modified for a military application, and
 - Does not have predominant civilian applications, and
 - Does not have a performance equivalent (defined by form, fit or function) to those of an article or service used for civil applications; or
 - Is specifically designed, developed, configured, adapted or modified for a military application, and has significant military or intelligence applicability such that control under this subchapter is necessary.

Defense service:

- Providing technical assistance (including training) to foreign persons (whether 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;
- Providing to foreign persons any technical data controlled under this subchapter (see below) whether in the U.S. or abroad;
- Military training of foreign units and forces, regular and irregular, including formal or informal instruction of foreign persons in the U.S. or abroad or by correspondence courses, technical, educational, or information publications and media of all kinds, training aid, orientation, training exercise, and military advice.

Technical Data:

Information required for the design, development, production, manufacture, assembly, operation, repair, testing, maintenance or modification of defense articles; Invention covered by a secrecy order; and software directly *related to a defense article*.

> 1. WHAT ARE EXPORT CONTROLS?

How do export controls work?

EAR – Dual Use Destination/End Use controls

- Exports of certain commodities (whether hardware, software, technology or technical data) identified on the Commerce Control List (CCL) with an Export Control Commodity Number (ECCN) require prior written authorization — an “export license” — or must meet an allowable exception.
 - Licenses take at least 30 plus days to obtain and are often issued with mandatory end use/user conditions.
- Licensing depends on three factors:
 - Type of item;
 - Reason(s) for control e.g., anti nuclear proliferation (NP), missile technology (MT), national security (NS), chemical biological control (CB), or several other types of control could be placed on it ;
 - Whether country exported to is controlled for an item with that level of control, based on CCL Country Chart.
- Commerce Control List (CCL) 15 CFR 774 Categories 0-9:
 - 0 Nuclear Materials, Facilities, Equipment
 - 1 Materials, Chemicals, Microorganisms, Toxins
 - 2 Materials Processing
 - 3 Electronics
 - 4 Computers
 - 5 Telecommunications and Information Security
 - 6 Lasers and Sensors
 - 7 Navigation and Avionics
 - 8 Marine
 - 9 Propulsion Systems, Space Vehicles and Related Equipment

> 1. WHAT ARE EXPORT CONTROLS?

EAR – Dual Use Destination/End Use controls (Continued)

- Within each category 0-9 above, items are arranged according to the same five groups, A-E below:
 - A Equipment, Assemblies and Components
 - B Test, Inspection and Production Equipment
 - C Materials
 - D Software
 - E Technology

ITAR - Military/Defense Controls

- Based on U.S. Munitions List (USML – 22 CFR 121) pertaining to definitions of defense article, service, or technical data defined above (including certain items “specially designed or modified for military application”): categories include:
 - Toxicological Agents/Equipment, Radiological Equipment
- Exports require prior “authorizations” based on item, design, end use or defense service activity for any export unless a specific exemption applies.
 - EAR Items exported in furtherance of an ITAR defense service require authorizations
 - **Note:** Certain countries allowable or licensable for EAR exports are per se prohibited for ITAR, and presumed denied for ITAR purposes: e.g., China.

***NOTE:**

Just because an item is purchased in the US and is commercially available, does not render it un-controlled for purposes of these regulations were it exported.

2. Export Compliance Risks Specific to Biomedical Research

Biomedical Research: Biological Agents and Equipment

Materials

Commerce Control List Category 1 (EAR) 1C351-354, 1C360

Controls in Category 1 of the Commerce Control List cover dual-use Materials, Chemicals, Microorganisms, and Toxins including:

- Human and Zoonotic Pathogens and Toxins
- Animal Pathogens
- Genetic Elements and Genetically Modified Organisms of Pathogens and Toxins
- Plant Pathogens
- Vaccines Against Toxins and Pathogens
- Immunotoxins Containing Human/Zoonotic Toxins
- Medical Products Containing Botulinum or Conotoxins
- Diagnostic/Food Testing Kits Containing Human or Zoonotic Toxins

Select Agent List

This list covers *domestically*-controlled toxins and is maintained by the CDC and APHIS. While Category 1 is almost entirely inclusive of everything on the Select Agent List, the same is not true in reverse. Some items controlled in Category 1 do *not* appear on the Select Agent List.

US Munitions List (ITAR) Category XIV

This Category covers Toxicological Agents, Including Chemical Agents, Biological Agents and Associated Equipment

- Subparagraph (b): “Biological Agents and biologically derived substances specifically developed or modified for the purpose of increasing their capability to produce casualties in humans or livestock, degrade equipment or damage crops”
- Subparagraph (g): Antibodies, polynucleotides, biopolymers or biocatalysts
- Subparagraph (h): Vaccines to protect against defense bioagents

> 2. EXPORT COMPLIANCE RISKS SPECIFIC TO BIOMEDICAL RESEARCH

Equipment in Support of Biomedical Research

Commerce Control List Category 2 (EAR)

- ECCN 2B352, Equipment capable of use in handling biological materials
 - Complete P3 or P4 facilities
 - Fermenters
 - Centrifugal Separators
 - Cross-flow Filtration Equipment & Components
 - Freeze-drying equipment
 - Protective and Containment Equipment
 - Aerosol Challenge Chambers
 - Spraying or Fogging Systems

US Munitions List (ITAR) Category XIV

- Subparagraph (f): Bioagent test, collection, detection, decontamination, disposal and protection equipment
- Commerce Control List Statement of Understanding re: Medical Equipment. For dual-use items designed for *treatment of patients*, export licenses are not required. However, absent specific exceptions, items used for *medical research* are still subject to controls.

Technologies Related to Pathogens and Toxins

Technologies used to produce the materials listed in CCL Category 1 are also controlled.

Examples of controls:

- Activity/items related to the design, development, production, stockpiling or use of a biological weapon. (Note: These will *always* require licensing.)
- Technology required for the development, production, or disposal of export- controlled pathogens, toxins and microbiological materials.
- Technology for the use/study of export-controlled pathogens, toxins, and microbiological materials should be taken on a case-by-case basis.

EAR/ITAR End User Controls/Prohibitions

Separate from above-referenced controls, government prohibits *exports to* or *export collaboration with* certain designated individuals and entities identified as export violators both in and outside the U.S.

- Compliance requirement to screen certain parties (for example foreign institutions, industrial sponsors) against government-published lists prior to export (Denied Parties List, Restricted Entities List, Debarred Parties List, Specially Designated Nationals List).

3. Current U.S. Government Enforcement Efforts

How Are Controls Enforced?

- Civil and criminal enforcement authority over EAR and ITAR violations, resulting in loss of export privileges, severe monetary fines (millions of dollars), prosecution (criminal) — against University *and/or faculty member or administrator* to whom violation is found attributable.
 - Agencies exercise broad enforcement discretion
 - 5 year look-back rule
 - Nationwide, several universities and medical campuses now under investigation
- Recent Criminal Prosecutions
 - Thomas Butler, Chief of Infection Disease Division, Texas Tech Dept. of Internal Medicine: Select Agent violations/export to Tanzania
 - J. Reece Roth, Professor Emeritus, University of Tennessee, Knoxville/technology transfer to foreign graduate students (China and Iran) contrary to explicit contractual provisions

4. Research-based Exclusions from Certain Control Requirements

“Exclusions”

Partially exempt research activities from *some but not all* of the export control licensing requirements, rendering export compliance easier to achieve, and faculty/administrators less vulnerable to violation. However, exclusions must be used knowledgeably/correctly; otherwise, licensing requirement is triggered, failure of which to obtain is an export control violation.

Fundamental Research Exclusion (FRE) – EAR/Public Domain -ITAR

Definition

Basic and applied research in science and engineering conducted at a U.S. university or research institution, the results of which ordinarily are published and shared broadly within the scientific community.

What is published information, or for ITAR purposes, in the public domain?

Generally accessible to the public through:

- Publication in periodicals, books, print, electronic, or other media available for general distribution (including websites that provide free uncontrolled access) or to a community of persons interested in the subject matter, such as those in a scientific or engineering discipline, either free or at a price that does not exceed the cost of reproduction and distribution;
- Readily available at libraries open to the public or at university libraries;
- Patents and published patent applications available at any patent office;
- Release at an open conference, meeting, seminar, trade show, or other open gathering held in the U.S. (under ITAR) or anywhere (under EAR). Note, a conference or gathering is "open" if all technically qualified members of the public are eligible to attend and attendees are permitted to take notes or otherwise make a personal record of the proceedings and presentations.
- ITAR: general descriptions/marketing material relating to function/purpose of defense article.

Fundamental Research Exclusion (FRE) – EAR/Public Domain –ITAR (continued)

Benefit

Even if results of the research might otherwise be export controlled under the EAR and therefore subject to deemed export restrictions as to who could participate in the research, the FRE generally allows anyone of any nationality access to the results of the research.

Caveat

Absolutely no restrictions can be accepted from a corporate or government sponsor that:

- Directly or indirectly prohibit dissemination or publication of research results, or
- Mandate foreign national restrictions as to who can access research.

Except for:

Limited pre-publication review by research sponsors is acceptable within a reasonable timeframe but only to:

- Prevent inadvertent divulgence of proprietary information or government classified information (as having been mutually defined) and provided by the sponsor, or
- Ensure that pre-defined proprietary content will not compromise the sponsor's patent rights.

Educational Information Exclusion - EAR and ITAR

“Educational information” released by instruction in catalogue courses or professional conferences where all technically qualified members of the public are eligible to attend and attendees are permitted to take notes of proceedings.

Non Disclosure Agreements (NDAs)

An NDA containing a confidentiality clause and/or an export control clause (should the data being provided be controlled) does not per se compromise FRE or public domain status, provided that:

- Where the purpose of the NDA is to safeguard proprietary background information and in no way restrict research results, the university/research institution can accept under its usual contractual standards.
- Where the purpose of the NDA is to safeguard both proprietary data and export controlled data or just export controlled data, PI and sponsor need to discuss amount of information and the extent to which the project can be performed with either no transfer of said data to the PI, or transfer to only one or two PIs, but not the balance of the research team — i.e., consistent with the data being used strictly for background purposes.
- Note: As a practical matter it is better not to accept export controlled data where it can be avoided. Accepting ITAR data, even for background purposes, will require the PI or researcher to assume the responsibility of safeguarding the technology from inappropriate IT and physical access.

Flow-down Provisions in Sub contracts

- Depends on exactly how the prime and subcontracts are written. Where the restriction is explicitly cited in the sub contract or explicitly incorporated by reference, the restriction would apply unless otherwise negotiated out.
- However, you cannot assume that just because a restriction is not referenced, it has not flowed down.

So When Do I Need a License?

- Shipment of Equipment Abroad – Since the FRE only applies to technology and technical data, a license may be necessary to export equipment depending on ITAR or EAR requirements.
- Carrying or transmitting export controlled technical data or development software - for example, loading cryptography development software or proprietary export controlled information on a laptop or sending it abroad to a destination for which the data is controlled.
- Distinguishable from exporting FRE data results (must be uncontrolled results only) which does not require a license

> 4. RESEARCH-BASED EXCLUSIONS FROM CERTAIN CONTROL REQUIREMENTS

What Can I Take with Me When I Travel?

Use License Exception TMP (Tools of Trade)

- Applies to usual and reasonable kinds/quantities of tools (commodities/software) for use by exporter.
- Must remain under effective control exporter or exporter's employee (physical possession, locked in safe, guarded).
 - Would generally not apply to laboratory equipment that cannot be protected.
- Must accompany exporter when traveling or be shipped within one month before departure or any time after departure, and be returned no later than one year post export.
- Exemption does not apply to OFAC-designated terrorist countries, such as Cuba and Sudan (See OFAC rules below).

OFAC Embargoed Country Rules: How Are They Different From Other Controls?

Office of Foreign Assets Control - 31 CFR 501 et seq:

- Places economic embargos and sanctions on transactions by U.S. persons involving specific countries (Cuba, Iran, Syria, N. Korea, and Sudan) by prohibiting without a license:
 - A broad range of services and transactions that benefit or provide value to those countries.
 - Export of products, software, and transfer of technical data.
 - Providing educational services and technical services, even where no monetary compensation occurs - see specific country regulations.
- Definition of U.S. Person includes:
 - Any person within the U.S. (including any non-U.S. entity that maintains an office or branch in the U.S.).
 - Any U.S. citizen or permanent resident alien, wherever physically located.
 - Any entity or institution organized under U.S. law, including foreign branches.
- Licenses can be obtained from OFAC on case-by-case basis, but terms must be strictly complied with.
 - Regulations permit attendance in U.S. of students from these countries with proper student visas, but employment is subject to U.S. funding restriction;
 - Certain restrictions apply to obtaining export licenses for proprietary export controlled source code.
 - Distance Learning programs subject to OFAC for providing a service.
 - Certain institutional and individual travel subject to restrictions.

5. Seven Practical Tools/Solutions to Minimize Individual and Institutional Risk

1. Plan Ahead

- Identify as early as possible when research requires shipment of materials or equipment
- Identify whether procured items are controlled, in the event they are ever shipped
- Determine whether FRE will apply b/c no contractual restrictions are accepted
- NDAs: make sure applicable only to background research

2. Where restrictions are accepted, classify research activity for purposes of deemed export rule

- Invention Disclosure: make sure export control plan in place during commercialization process
- Utilize Technology Control Plan for Physical and IT Security

3. Develop a set of work instructions addressing the following:

- Screening end users
- Classification and licensing (EAR and ITAR)
- Procurement and Shipping
- Re-export (knowledge of secondary destination)
- Visitors Access to controlled areas (may be part of TCP)
- Hand Carried Item/Travel
- Recordkeeping

4. Institution should designate “lead” export control administrator as a knowledgeable “go-to” person

- In large or decentralized organizations, consider using Export Control Focal Points as “go-to” resources

5. Develop a comprehensive export control policy addressing

- Sponsored Programs (government and industry)
- Consulting Projects
- International Collaborations

6. Conduct a Risk Assessment to identify key sensitive areas

- Assessment can occur at the department level and/or address specific programs, or activities

7. Conduct awareness trainings

- Trainings should be somewhat customized to leadership group, researchers, or administrators

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