Where the Healthcare Research and U.S. Export Regulations Meet: Do You Know What is Coming Into and Out of Your Labs?

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What Are Export Control Regulations?

■ Export Control Regulations prohibit the unauthorized "export" of certain controlled ITEMS, INFORMATION OR SOFTWARE to foreign persons or entities in the U.S. and abroad

■ ITEMS= Tangible things, materials, equipment or hardware

■ INFORMATION = "Technical Data" such as models, formulae, engineering designs or "Technical Assistance" such as training or instruction

■ SOFTWARE = Computer programs or microprograms in either "Source Code" (programming statements) or "Object Code" (machine-readable instructions)

What is an "Export"?

- Shipment of controlled tangible items or goods outside of the US

- Transmission (electronic or digital) of controlled item, software or information related to controlled item outside of the US

- Use or application of controlled technology on behalf of, or for the benefit of, any foreign person or entity, either in U.S. or abroad

- Release or disclosure (including verbal or visual) of any controlled technology, software or technical data, either in U.S. ("deemed export") or abroad

Deemed Exports

- The transfer of technology to a foreign person in the U.S. is "deemed" to be an export to that individual's home country

- The information can take the form of data or technical assistance

- Release of certain controlled software source code and technology within the U.S. may be a "deemed export"

- Licensing issues may arise when controlled technology is disclosed to foreign students, foreign national laboratory staff, visiting researchers from abroad and those on site visits

Who is a "Foreign Person"?

- A "foreign person" is anyone who is not a "U.S. person"

- A "U.S. person" is either:

  - A U.S. citizen, lawful permanent resident alien ("Green Card Holder"), refugee, protected political asylee or someone granted temporary residency under amnesty or Special Agricultural Worker provisions; or

  - Any juridical person of the U.S. (i.e. organizations under the laws of the United States or any jurisdiction within the U.S., including foreign branches)

Who is a Foreign Person? (2)

- Examples of foreign persons:

  - ☐ Individuals in the U.S. in Non-Immigrant Status (H-1B, F-1, J-1)

  - ☐ Any branch of a foreign government

  - ☐ Any foreign corporation or group that is not incorporated or organized to do business in the U.S.

The Regulations

- **State Department - International Traffic in Arms Regulations (ITAR)**

  - ☐ Covers military and space-related technologies
  - ☐ Administered by the Directorate of Defense Trade Controls (DDTC)

- **Commerce Department - Export Administration Regulations (EAR)**

  - ☐ Covers commercial and "dual use" technologies
  - ☐ Administered by the Bureau of Industry and Security (BIS)

- **Treasury Department – Various Economic and Trade Sanctions Regulations**

  - ☐ Regulates transfer of assets or services to those countries
  - ☐ May prohibit travel/other activities with sanctioned countries & persons even when exclusions to EAR/ITAR apply
  - ☐ Administered by the Office of Foreign Assets Control (OFAC)

Export Control Exclusions

- Public Domain Exclusion (ITAR)

- Publicly Available Exclusion (EAR)

- Educational Information Exclusion

- Fundamental Research Exclusion

Public Domain Exclusion (ITAR)

- US Munitions-Listed information and software that is generally accessible and available to the public through/at one or more of the following:

  - Fundamental research in science and engineering per Part 120.11 - performed at an accredited institution of higher learning **in the US**;
  - Libraries open to the public;
  - Sales at newsstands or bookstores;
  - Subscriptions available without restriction;
  - Published patents available at any patent office;
  - Unlimited distribution at conferences, meetings, seminars, trade shows or exhibitions **in the US** that are generally available to the public; **and/or**
  - Websites that are accessible to all members of the public, free of charge, and where the university does not have knowledge or control over who visits the site or downloads the information or software

Publicly Available Exclusion (EAR)

- Commerce Control-Listed information and software that is generally accessible to the interested public in any form through/at one or more of the following:

  - Fundamental research in science and engineering per Part 734.8 – may have been generated outside of the US;
  - Publication in periodicals, books, print, electronic, or any other media available for general distribution either free or at a cost not exceeding the cost of reproduction and distribution (allows for a reasonable profit);
  - Libraries open to the public or from university libraries;
  - Through subscriptions which are available without restriction either free or at a cost not exceeding the cost of reproduction and distribution (allows for a reasonable profit);

Publicly Available Exclusion (EAR) (2)

- ☐ Published patents and open (published) patent applications available at any patent office;

- ☐ Unlimited distribution at conferences, meetings, seminars, trade shows or exhibitions **in the US or abroad** that are generally accessible to the public for a fee reasonably related to the cost, and where attendees may take notes; **and/or**

- ☐ Websites which are accessible to all members of the public, free of charge, and where the institution does not have knowledge or control of who visits the site or downloads the information or software.

Educational Information Exclusion

- ITAR – Export Controls do not apply to information concerning "general scientific, mathematical or engineering principles commonly taught in schools, colleges and universities."

- EAR – Export Controls do not apply to "educational information" released by instruction in catalog courses and associated teaching laboratories.

Fundamental Research Exclusion

- Covers most basic research at colleges and universities
- Also applies to corporate and lab dual use research
- Stated US government policy via NSDD 189
- Defined by Export Administration Regulations (EAR) at Part 734.8:

> "basic and applied research in science and engineering, where the resulting information is ordinarily published and shared broadly within the scientific community. Such research can be distinguished from proprietary research and from industrial development, design, production, and product utilization, the results of which ordinarily are restricted for proprietary reasons or specific national security reasons"

Fundamental Research Exclusion (2)

- The fundamental research exclusion will not apply if the organization accepts any restrictions on the publication of research results, other than a brief (~ 90 day) advance review by sponsors to:

  - Prevent divulging propriety information provided to the investigator by the sponsor
  - Insure that publication will not compromise patent rights of the sponsor

- Clinical trials are an exception – long publication delays

  - Generated Data vs. Research Results
    - Quality Control not Market Advantage

Fundamental Research Exclusion (3)

- Fundamental Research Exclusion is destroyed by any clause that:

  - Gives the sponsor the right to approve publications
  - Restricts participation of foreign nationals in conduct of research by precluding access to research results

- The Fundamental Research Exclusion is destroyed by such clauses regardless of sponsorship (federal, private or non-profit)

Fundamental Research Exclusion (4)

- **This exclusion applies to INFORMATION and SOFTWARE CODE, not to tangible ITEMS**

  - No export license required to share FRE information or software code with foreign nationals
  - No export license required to send or transfer FRE information abroad
  - No export license required to transmit or transfer FRE software code overseas
    - Strong encryption code is the exception

It's Export Controlled If It's…

- Not subject to an Export Control Exclusion AND

- On the U.S. Munitions List (USML)
  - ITAR 22 CFR 121.1
  - Anything that is identical in "form, fit and function" to a munitions item or that has a predominant military application even if not on the USML

- On the Commerce Control List
  - EAR 15 CFR 774

- A Defense Service (ITAR)
  - e.g., training on how to use defense articles

- "Technology" (EAR) or "Technical Data" (ITAR)
  - Information beyond basic and general marketing materials for the use, development or production of controlled items or materials

- EAR99 - a "catch-all" category for items/software/info subject to the EAR but not listed on the CCL

When are Export Licenses Required?

- Under (ITAR) State Department jurisdiction a license is always required unless an exemption is in place

- Under (EAR) Commerce Department a license is required only when specified for a particular item and a particular country and if an exception is not available

- Under OFAC (Treasury) jurisdiction, a license is always required with only a couple of exceptions, such as informational materials

Situations That Raise "Red Flags"

- Terms & conditions that destroy Fundamental Research Exclusion (FRE)

  - Terms that limit access to or dissemination of research results

    - Sponsor cannot have the right to approve or delay publications for competitive market advantage
    - Sponsor cannot pre-approve foreign nationals for work on research
    - Sponsor cannot restrict access by foreign nationals to research results

- Restriction also raises "Openness in Research" policy issues for colleges and universities

Red Flags: Proprietary Restrictions

- Items, information or software that are either:

    - a) proprietary and not in public domain

    - b) marked "export controlled" or

    - c) entail access/dissemination restrictions

        - Not subject to FRE or other exclusions

- Proprietary information may be needed in the conduct of life science research

Red Flags: Proprietary Restrictions (2)

- ☐ Commercial Licensing Agreements
  - ■ Software/Hardware export control clauses

- ☐ Material Transfer Agreements
  - ■ Intent is Driver – Quality Control for Research vs. Proprietary Advantage

- ☐ NDAs/Confidentiality Agreements
  - ■ Primary export control compliance risk for universities

Red Flags: Dual Use Pathogens and Toxins

- **Commerce Control List (EAR)**
  - Category 1: Dual Use Materials, Chemicals, Microorganisms, and Toxins
    - 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
    - Diagostic/Food Testing Kits Containing Human or Zoonotic Toxins

Red Flags: Defense-Related Biological Agents

- **US Munitions List (ITAR)**
  - ☐ Category XIV: 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 (f): Bioagent test, collection, detection, decontamination, disposal and protection equipment
    - Subparagraph (g): Antibodies, polynucleoides, biopolymers or biocatalysts
    - Subparagraph (h): Vaccines to protect against defense bioagents

Red Flags: Technologies Associated w/Pathogens and Toxins

- Any US Person activity that is directly or indirectly related to the design, development, production, stockpiling or use of a biological weapon

  □ Will always require an export license – no exceptions

- Technology "required" for the development or production or disposal of export controlled pathogens, toxins and microbiological materials

  □ "Required" = that portion of the technology that is peculiarly responsible for achieving the development, production or disposal of the pathogens, toxins and materials

- Technology for the "use" (i.e. examination) of export controlled pathogens, toxins and microbiological materials is not subject to deemed export rules

Red Flags: Life Sciences-Related Tangible Exports

- **Life-Sciences-Related Tangible Exports**
  - Any physical export that is directly or indirectly related to the design, development, production, stockpiling or use of a biological weapon
    - Will always require an export license – no exceptions
  - Reagents incorporating controlled pathogens/toxins
  - Life Sciences electronic test, measurement, or diagnostic equipment
  - Computers/Laptops

Red Flags: Tangible Exports (2)

- Equipment and devices taken or shipped abroad that contain "strong" encryption code

  - 56-bit symmetric – USG notification required for dual use code
  - If possible, leave code in US and access remotely

- No Export Licenses Required for Dual Use Items Designed for Treatment of Patients (EAR99)

  - See Supplement No. 3 to Part 774 of EAR - Statements of Understanding

    - Excludes Items and Software for Medical Research

A Compliance Program is Required for Exporters

- **The Export Compliance Program**

  - ☐ Provides a written, documented process for communicating the terms & conditions of an approved agreement

  - ☐ Provides a process for *authorized exemption acceptance*

  - ☐ Provides a process for obtaining a license and approval of the terms and conditions ("limitations and provisos") by requisite business unit personnel involved in the export transaction

  - ☐ Provides a process for management of license agreements, managing technology control plans, and monitoring for compliance

Export Compliance Program

- Five basic tenets are included in an Export Compliance Program. For properly implementing agreements, a plan must:

  - ☐ Be written and documented
  - ☐ Include training of essential personnel
  - ☐ Integrate export activity logs
  - ☐ Track compliance to provisos & limitations
  - ☐ Contain user acknowledgments of provisos & limitations

Export Compliance Program (2)

- Fundamental elements of a compliance program include:

  - ☐ Export Compliance Management Policy
  - ☐ Export compliance personnel
  - ☐ Party and country screening
  - ☐ Proliferation screening
  - ☐ In-house compliance **Training** program
  - ☐ Recordkeeping
  - ☐ Monitoring and Internal Review
  - ☐ Foreign National Technology Control Plan

Export Compliance Program When You Don't Expect to Export

■ Fundamental elements of a compliance program include:

☐ Export Compliance Management Policy

☐ Definition of export compliance roles and responsibilities

☐ Party and Country Screening

☐ In-house Compliance Training Program

☐ Documentation of Exemptions

☐ Recordkeeping

☐ Monitoring and Internal Review