

Keys to Implementing an Export Controls Compliance Program
Health Care Compliance Association
Research Compliance Conference
June 7, 2016



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Questions to Consider



- Does your Department/PI ship samples/equipment/technology internationally?
- Does your Department/PI accept foreign nationals as lab staff?
- Does your Department/PI have grants with DoD or DARPA?
- Do your faculty travel to embargoed countries?

HMS Approach

- **“START FROM SCRATCH” – ASSUME NO ONE KNOWS ANYTHING ABOUT EXPORT CONTROLS**
- **FORM WORKING GROUP FROM DEPARTMENTS THAT MAY BE EFFECTED BY EXPORT CONTROLS (IT, ENVIRONMENTAL HEALTH & SAFETY, SPONSORED PROGRAMS, BIOSAFETY, TECH. TRANSFER, GLOBAL HEALTH DEP'T)**
- **ONE GOAL: RAISE AWARENESS WITHIN COMMUNITY**

Harvard Medical School



MD STUDENTS 708
DMD STUDENTS 146
PHD STUDENTS 815
TOTAL TENURED AND TENURE-TRACK FACULTY 183
APPROXIMATE NO. OF RESEARCH FELLOWS 940
APPROXIMATE % OF RESEARCH FELLOWS WHO ARE FOREIGN NATIONALS 65%
FY '15 RESEARCH OPERATING REVENUE FROM GRANTS/CONTRACTS: \$270M

HMS Approach Cont.



- Take control, ownership, dedicate resources
- Assess vulnerabilities and identify obvious risks
- Gain support from school leadership
- Buy-in from departments / faculty
- Identify opportunities to raise awareness
- Develop checklists, literature, email address (export_controls@hms.harvard.edu)
- Obtain tools (i.e. Visual Compliance)

Pre-Award Questions to Ask



- Does your research project involve:
- Shipping equipment to a foreign country?
- Purchasing equipment that is ITAR controlled?
- Collaborating with foreign colleagues in foreign countries?
- Training foreign nationals in using equipment?
- Working with or traveling to a country subject to a U.S. boycott?
- References to “EAR”, “OFAC” or “ITAR” in the terms and conditions?
- Is the sponsor requiring pre-approval rights over publications or the participation of foreign national students?

Fundamental Research



- Fundamental research is excluded from export controls
 - EAR: “...university research [is] normally...considered fundamental”
 - ITAR: “basic and applied research in science and engineering”
- Requirements:
 - No unreasonable restrictions on publication
 - ✦ Except brief review for proprietary information or patent rights
 - ITAR: no access/dissemination controls for government-funded research
 - Note: encryption software is a special case

Publication restrictions



- Restrictions or prior approval may invalidate FRE
 - Includes MTAs, Non-disclosure agreements
 - “Review” can be OK, “approval” is not
- “DFAR 252-204-7000 Disclosure of Information”
 - “The contractor shall not release to anyone outside the Contractor’s organization any unclassified information... pertaining to any part of this contract or any program related to this contract, unless
 - ✦ “The contracting Officer has given **prior written approval**; or
 - ✦ “The information is otherwise in the public domain before the date of release.”

Access restrictions



- Government and corporate grants/contracts may limit access
 - Examples: “US only”, “no foreign nationals”
 - Under the ITAR, the FRE will be lost if there are access and dissemination controls
- Agencies may preclude or limit access by foreign nationals to research based on the export control laws
 - May require prior approval
 - Under ITAR, no license available if a foreign national is from certain restricted countries (22 CFR 126.1)

Shipping Internationally



**Department of Commerce
Bureau of Industry Standards**



1. Nuclear and Miscellaneous
2. Materials, Chemicals, Microorganisms, Toxins
3. Materials Processing
4. Electronics
5. Computers
6. Telecommunications
7. Information Security
8. Sensors and Lasers
9. Marine
10. Aerospace and Propulsion

Registration with BIS



- **SNAP-R Registration**
 - Requires Corporate Identification Number (CIN)
 - Designate Account Manager(s)

Information Required for BIS License Application

- ECCN

A key in determining whether an export license is needed from the Department of Commerce is finding out if the item you intend to export has a specific Export Control Classification Number (ECCN).

ECCNs are five character alpha-numeric designations used on the Commerce Control List (CCL) to identify dual-use items for export control purposes. An ECCN categorizes items based on the nature of the product, i.e. type of commodity, software, or technology and its respective technical parameters.

Human and zoonotic pathogens and toxins ECCN 1C351

Section A:

Viruses identified on the Australia Group (AG) “List of Biological Agents for Export Control,” as follows:

- Andes virus;
- Chapare virus;
- Chikungunya virus;
- Choclo virus;
- Congo-Crimean haemorrhagic fever virus (a.k.a. Crimean-Congo haemorrhagic fever virus);
- Dengue fever virus;
- Dobrava-Belgrade virus;
- Eastern equine encephalitis virus;
- Ebola virus;
- Guanarito virus;
- Hantaan virus;

ECCN 1C351



- | | |
|---|--|
| <ul style="list-style-type: none"> • Hendra virus (Equine morbillivirus); • Japanese encephalitis virus; • Junin virus; • Kyasanur Forest virus; • Laguna Negra virus; • Lassa fever virus; • Louping ill virus; • Lujo virus; • Lymphocytic choriomeningitis virus; • Machupo virus; • Marburg virus; • Monkey pox virus; • Murray Valley encephalitis virus; • Nipah virus; • Omsk haemorrhagic fever virus; | <ul style="list-style-type: none"> • Oropouche virus; • Powassan virus; • Rift Valley fever virus; • Rocio virus; • Sabia virus; • Seoul virus; • Sin nombre virus; • St. Louis encephalitis virus; • Tick-borne encephalitis virus (Far Eastern subtype, formerly known as Russian Spring-Summer encephalitis virus); • Variola virus; • Venezuelan equine encephalitis virus; • Western equine encephalitis virus; or • Yellow fever virus. |
|---|--|

Information Required for BIS License Application



- **Destination of Export**
- **Name of Recipient / Intermediary**
- **Description of Export**
- **Volume / quantity of export**
- **Value of Export (default value of \$1.00)**
- **Intended Use of Export (“basic research”)**
- **Confirmation of BL-2 Conditions**

Post License Application



- Login regularly to check status of license
- Often BIS seeks clarification or additional information
- If no license is required, BIS inform of such

Export License
D1042383
 Validated: December 22, 2015
 Expires: December 31, 2019



UNITED STATES DEPARTMENT OF COMMERCE
BUREAU OF INDUSTRY AND SECURITY
 WASHINGTON, D.C. 20230

Unless limited by a condition set forth below, the export, reexport or transfer (in-country) authorized by this license is for the item(s), end-use(s), and parties described in the license application and any letters of explanation. The applicant is responsible for informing the other parties identified on the license, such as ultimate consignees and end-users, of the license's scope and of the specific conditions applicable to them. BIS has granted this license in reliance on representations the applicant made in the license application, letters of explanation, and other documents submitted.

Applicant Reference Number: DDD4444

APPLICANT: H107815
 HARVARD MEDICAL SCHOOL
 FACULTY AND RESEARCH INTEGRITY
 25 SHATTUCK ST., GORDON HALL ROOM 1
 BOSTON, MA 02115
 United States

PURCHASER:

ULTIMATE CONSIGNEE:
 Chinese Center for Disease Control
 Changbai Road 155
 Changping
 Beijing 102206
 China

INTERMEDIATE CONSIGNEE:


QTY	DESCRIPTION (May Include Product Name or Model Number)	ECCN	TOTAL PRICE
1	Less than 5 microliters in an agar gel of <i>Vibrio cholerae</i> O37 serogroup strain V52 with the following genes deleted from the chromosome: <i>rtxA</i> , <i>hlyA</i> , <i>hpaA</i>	1C351	\$1.00
TOTAL:			\$1.00

The Export Administration Regulations require you to take the following actions when exporting under the authority of this license.

- A. Record the Export Commodity Control Number in the block provided in the Automated Export System (AES).
- B. Record your validated License Number in the block provided by AES.
- C. Place a Destination Control Statement on all bills of lading, airway bills, and commercial invoices.

CONDITIONS:

1. The applicant must obtain from ultimate consignee a written communication, before shipment, acknowledging and accepting all license terms and conditions. This document should be available to U.S. Government officials upon request.

<p>Export License D1042383 Validated: December 22, 2015 Expires: December 31, 2019</p>		<p>UNITED STATES DEPARTMENT OF COMMERCE BUREAU OF INDUSTRY AND SECURITY WASHINGTON, D.C. 20230</p>
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I. The applicant must establish and document a chain of custody procedure to ensure that only the authorized person representing the ultimate consignee can take receipt of the exported item(s). If the authorized person does not receive the exported item(s), the ultimate consignee must immediately notify the Bureau of Industry and Security, Office of Enforcement Analysis, Room 4066, 1401 Constitution Ave, NW, Washington, D.C. 20230. This office may be contacted by telephone at (202) 482-4255 or facsimile at (202) 482-0971.

II. This office may be contacted by telephone at (202) 482-4255 or facsimile at (202) 482-0971.

III. The applicant must verify that the ultimate consignee laboratory/facility meets the following security requirements for handling of viruses/bacteria in a Biosafety Level 2 laboratory/facility: A. Access to the laboratory is limited or restricted at the discretion of the laboratory director when experiments are in progress. B. Persons who are at increased risk of acquiring infection, or for whom infection may have serious consequences, are not allowed in the laboratory. C. The laboratory director has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory or animal rooms. D. The laboratory director establishes policies and procedures whereby only persons who have been advised of potential hazards and meet specific requirements may enter the laboratory. E. A biohazard sign must be posted on the entrance to the laboratory when etiological agents are in use. Appropriate information to be posted includes the agent in use, the biosafety level, the required immunizations, the investigators name and telephone number, any personal protective equipment that must be worn in the laboratory, and any procedures required for exiting the laboratory.

IV. The ultimate consignee will maintain logbooks that track the storage and use of the cultures and subcultures and must allow access to the logbooks as requested by the Department of Commerce.

V. The consignee must notify the applicant and the U.S. Department of Commerce, Bureau of Industry and Security (BIS), if the biological agents, or cultures of the biological agents are lost or stolen.

VI. The cultures and derived subcultures of the exported viruses/bacteria and genetic variants will be destroyed following certification of the completion of the project by the collaborators.

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International Travel



- **Shipped v. Carried Items:** Export-control laws do not distinguish between an item that is shipped and an item that is carried. Thus, *if it is unlawful to ship an item to a certain country without a license, it is also unlawful to take it with you.*
- **Destination:** *Your destination determines what export controls or regulations apply.* Contact your Institute's Export Control Officer or Office of General Counsel to determine whether your destination is subject to a sanctions program. Additionally, your arrival country may have import controls.
- **Restricted Individual/Entities:** Foreign individuals and entities may also be subject to sanctions. Before collaborating with a foreign national/entity, or presenting your research at an international conference, contact your School's export control officer or Office of General Counsel to ensure that the individuals/entities you are collaborating with, or presenting to, are not included on a sanctions list.
- **Money:** If you are traveling to a sanctioned country, *you may need a license to spend certain funds in that country.* Additionally, certain countries restrict how much money may be brought into or out of the country. The [International Air Transport Association \(IATA\)](#) website provides a list of currency rules.
- **Shipping Items Back:** Foreign countries may have their own export controls and US Customs enforces import controls.

Travel with Computing Devices

- **Electronic Devices and Encryption Software**

Taking a laptop abroad, allowing a person in a foreign country to use the laptop or permitting a foreign national access to the laptop in the U.S. may raise export control issues.

- **Before taking your laptop abroad:**

Consult IT and/or Office of General Counsel and review the software and data on your laptop to ensure that you are not taking out of the country any controlled software or technical information. This also applies to global positioning systems (GPS.)

- **Does this mean I can't take my laptop abroad?**

A licensing exception may apply to the export of a laptop or GPS, which may enable you to take a laptop abroad without violating export controls. Faculty who wish to take their laptops out of the country may be able to do so under the license exception for temporary export (TMP) if the laptop meets the requirement for "tools of trade" and remains under the control of the researcher, or the baggage (BAG) license exception covering personal items that are owned by the researcher and intended only for their personal use. **These License Exceptions might not apply if items are shipped or carried to certain sanctioned countries.**

Federal Corrupt Practices Act Compliance

- The Foreign Corrupt Practices Act (FCPA) is a U.S. federal law that prohibits the exchange of "anything of value" to a foreign official for the purpose of "securing any improper advantage" in obtaining, retaining or directing business (e.g. – decision to award a contract to research institution).
- "Anything of value" may extend past cash payments to include gifts and other consideration.
- **Enforcement:**
 - Department of Justice (DOJ) – non profits
 - Securities and Exchange Commission (SEC) – for profits

FCPA Compliance



- The FCPA prohibits the offer, promise, authorization and/or payment of money or other items of value for *a corrupt purpose*: attempting to influence the acts or decision making of foreign government officials either directly or indirectly to secure an improper advantage.
- *Items of value* encompasses both monetary and non-monetary exchanges, such as travel and entertainment or training, scholarships or employment opportunities (e.g. employing the child of a foreign official to curry favor). It is also important to emphasize that there is no monetary threshold, any exchange of value constitutes a violation of the FCPA.
- The FCPA also states that we are responsible for the actions of our contractors, agents and employees. For example: if a research institution had a contractor facilitating the development of an overseas campus and the contractor offered a bribe to a foreign official without the institution's knowledge, the U.S. institution would still be responsible for the acts of the contractor.
- It is worth noting that the FCPA provides an exception for facilitating payments, such as expediting a visa application, much like one may pay to have a passport application expedited here in the United States. For clarity, it is not permissible for a payment to be made for an approval. It is never allowable to provide payment to obtain a favorable decision. Caution should be exercised when contemplating a facilitating payment.

Screening for Specially Designated Nationals



SANCTIONS: SDNs



It is a criminal offence for a US person to make funds directly or indirectly available to individual, entities or groups listed in the Specially Designated National List.

Larger number of SDN's
ALBANIA, BANGLADESH, BOSNIA, CAMBODIA, COLUMBIA,
GHANA, KOSOVO, KUWAIT, MEXICO, PAKISTAN AND
PALESTINE

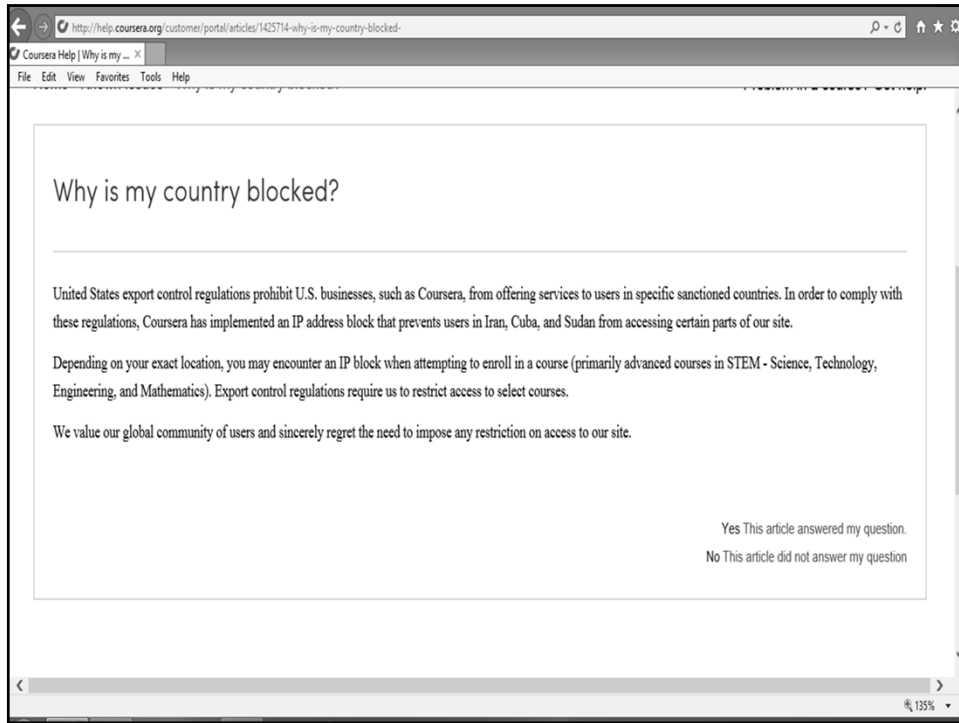
US persons are also prohibited from dealing with any entity which is 50% owned by an SDN.

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Activities Requiring SDN Screens




- Enrolling foreign nationals in:
 - ✦ Professional or continuing education courses,
 - ✦ Executive education programs, or
 - ✦ Massive Open On-line Courses;
- Otherwise providing services to or receiving funds from foreign nationals;
- Purchasing equipment or services from a foreign corporation;
- Conducting research outside of the U.S; and
- Engaging in international research collaborations.



When Should You Screen?

- Screen at the beginning and end of the collaboration/enrollment/order/shipping process;
- For purchase orders, ideally at quote stage, then at the time of shipment;
- Be wary of “close matches.” Investigate thoroughly.



The illustration shows a group of seven stylized human figures standing in a line. A magnifying glass is positioned over the central figure, symbolizing a focus on a specific individual or a detailed investigation within a group.

Export Control Licensing & Screening Tools



- Visual Compliance
<https://www.visualcompliance.com/>
- Amber Road
<http://www.amberroad.com/solutions/export-management.shtml>

Trends Noticed at HMS



- Movement towards non-NIH awards (DoD / DARPA)
- Export control related clauses appearing in subcontracts, non-disclosure agreements; collaboration agreements
- Use of export controlled supplies / equipment
- Presence of foreign nationals
- Registration with the Department of State (TBA)

Brochure

What's controlled and to where?

OFAC Equipment, software, chemicals, biological agents, technology designed for military use/ use in outer space, technology on U.S. Munitions List

EAR for 22 Countries Equipment or encrypted software, equipment, software or technology on the Commerce Control List; Information or instruction about software, technology, or equipment on the Commerce Control List

EAR for Group B Countries—including India and Israel Equipment or encrypted software, equipment, software or technology on the Commerce Control List; Information or instruction about software, technology, or equipment on the Commerce Control List

No License Required OK for all but Embargoed countries Most basic research results—Fundamental Research Not military or designed or modified for military use Not on Commerce Control List

Adapted from Georgia Tech Research Corporation Export Control Powerpoint presentation

Traveling with your Laptop

Taking a laptop abroad, allowing a person in a foreign country to use the laptop or permitting a foreign national access to the laptop in the U.S. may implicate export control issues.

Before taking your laptop abroad: Review the software and data on your laptop to ensure that you are not taking out of the country any controlled software or technical information. This also applies to global positioning systems (GPS). DRC can assist you with this review.

Why does bringing my laptop abroad potentially raise export control issues? Laptops and GPS devices, and their underlying software, are covered by the EAR and, in some cases, by the ITAR. Export regulations vary based on the country to which a researcher is traveling and the purpose for which he or she intends to use the laptop or GPS.

Does this mean I can't take my laptop abroad? A licensing exception may apply to the export of a laptop or GPS, which may enable you to take a laptop abroad without violating the EAR or ITAR. Excluding embargoed countries, faculty who wish to take their laptops out of the country to use in a research project that qualifies as fundamental research may be able to do so under the license exception for temporary export (TMP) if the laptop meets the requirement for "tools of trade" and is under the control of the researcher, or the baggage (BAG) license exception covering personal items that are owned by the researcher and intended only for their personal use. **You must contact DRC before using either of these license exceptions, as they are subject to record-keeping requirements.**

The TMP License Exception provides that when those items (and related technology and software) are: (i) being used for professional purposes, (ii) returned within 12 months, (iii) kept under effective control of the exporter while abroad (e.g., kept in a hotel safe or other secured space or facility), and (iv) other security precautions are taken against unauthorized release of technology (i.e., use of secure connections, password systems, and personal firewalls), then the TMP License Exception may apply. The License Exception might not apply if items are shipped or carried to certain OFAC sanctioned countries. If you have any questions about the use of this TMP exception, please contact DRC.

Harvard Medical School Export Control Compliance

Office of Research Compliance
(617) 432-3884
export_control@hms.harvard.edu
<http://www.hsh.harvard.edu/research/export-controls/index.html>

Brochure – reverse side

What do Universities export?

Mostly knowledge. Under the export regulations, the transfer of technology or technical data is considered an export even when it occurs inside the U.S. Because openness of research and freedom of access and dissemination of information for the advancement of scientific discovery is encouraged at Harvard, there are many avenues for export. Much of the information in the University environment is considered within the public domain and is therefore not of concern.

Activities that might necessitate an export control license include:

- International research collaborations;
- International shipments of certain viruses, equipment, software, or technology;
- Diversees travel, including presenting at conferences and/or bringing a laptop abroad;
- Provision of financial assistance to an embargoed country or person or entity that is considered a blocked or sanctioned party;
- Provision of professional services to a person or entity that is a blocked or sanctioned party or individual from an embargoed country.

Deemed Exports

In addition to regulating the export of actual goods abroad, the U.S. export control laws govern the export or release of technical data or technology to a foreign national, whether it occurs in the U.S. or abroad. Technology, know-how, and non-encryption source code that is released to a foreign national within the U.S. is "deemed" to be an export to the country where the person is a resident or citizen and could be subject to licensing requirements.

Export Control Regulations

US Department	Responsible	Regulations	Items Controlled
Treasury	Office of Foreign Assets Control (OFAC)	Foreign Assets Control Regulations (FACR)	Sanctions programs can govern travel abroad; transactions with foreign individuals and entities or in specific foreign countries, and export and import of items.
Commerce	Bureau of Industry and Security (BIS)	Export Administration Regulations (EAR)	Dual use goods, software, and technology predominantly civilian in nature but may include military applications. Antispyware provisions.
State	Directorate of Defense Trade Controls (DDTC)	International Traffic in Arms Regulations (ITAR)	Defense articles and technical data, data, software or information specifically designed, developed, or modified for military or intelligence application. Defense services.

Exclusions to the Deemed Export Rule

HMS takes advantage of a number of exclusions in the regulations and thereby can sometimes avoid the necessity of securing a deemed export license. If one of the exclusions applies, no deemed export license would be required.

The most common exclusions are for "fundamental research" and "educational information." In general, if a visa applicant will be conducting basic or applied research in science and engineering at HMS and the resulting information is ordinarily published and shared broadly in the scientific community, the research will fall under the fundamental research exclusion. In general, the release of information by instruction in catalog courses and associated teaching laboratories is eligible for the educational information exclusion.

Frequently Asked Questions

Our department doesn't do any exporting. Why do I need to be concerned about export controls? Any item that is sent from the U.S. to a foreign destination is an export. "Items" include commodities, software, technology, and information. How an item is transported outside of the U.S. does not matter. Some examples include:

- Items sent by regular mail or hand-carried on an airplane, like a laptop;
- Software uploaded or downloaded from an internet site;
- Technology transmitted via e-mail or during a telephone conversation.

How do I determine if an export license is needed? Work with the Compliance Office to make this determination. Determining whether an export is subject to a licensing requirement is a complicated process. Whether something is controlled for export is not intuitive. License requirements are dependent upon an item's technical characteristics, the destination, the end use, and the end user.

How do I apply for an export license? If it is determined that your activity requires an export license, your Compliance Officer will work with you to submit a license request to the appropriate regulatory body on your behalf. It is important to note that obtaining an export license from the Commerce Department usually takes 30 days; a license from the State Department can take several months; and a license from the Treasury Department can take 3-6 months. Although there is no guarantee that a license will be granted, all three regulatory licenses have granted licenses to Harvard for the conduct of research.

Thank You



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**“I HAVE FOUGHT THE GOOD FIGHT. I HAVE
FINISHED THE RACE. I HAVE KEPT THE
FAITH.” 2 TIMOTHY 4:7**