

Keys to Implementing an Export Controls Compliance Program
Health Care Compliance Association
Research Compliance Conference
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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.

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- 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

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- 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

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**Department of Commerce
Bureau of Industry Standards**

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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

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- 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.
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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

<p>Export License D1642383 Validated: December 22, 2015 Expires: December 31, 2019</p>		<p>UNITED STATES DEPARTMENT OF COMMERCE BUREAU OF INDUSTRY AND SECURITY WASHINGTON, D.C. 20530</p>												
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.														
<p>Applicant Reference Number: DDH444</p>														
<p>APPLICANT: H107815 HARVARD MEDICAL SCHOOL FACULTY AND RESEARCH INTERGRITY 38 SHAW FLOOR ST., CORCORAN HALL, ROOM 1 BOSTON, MA 02115 United States</p>	<p>PURCHASER:</p>													
<p>ULTIMATE CONSIGNEE: Chinese Center for Disease Control Changshu Road 155 Changping Beijing 102206 China</p>	<p>INTERMEDIATE CONSIGNEE:</p>													
<table border="0" style="width: 100%;"> <tr> <th style="text-align: left;">COMMODITIES:</th> <th style="text-align: left;">DESCRIPTION (May include Product Name or Model Number)</th> <th style="text-align: left;">EICDN</th> <th style="text-align: left;">TOTAL PRICE</th> </tr> <tr> <td style="text-align: left;">1</td> <td style="text-align: left;">Less than 8 nucleotides in an oligo pool of Yersinia enterocolitica O3F4 antigens within Y10 with the following genes deleted from the chromosome: rfaA, rfaB, rfaC</td> <td style="text-align: left;">1038E1</td> <td style="text-align: left;">\$1.00</td> </tr> <tr> <td colspan="3" style="text-align: right;">TOTAL:</td> <td style="text-align: right;">\$1.00</td> </tr> </table>			COMMODITIES:	DESCRIPTION (May include Product Name or Model Number)	EICDN	TOTAL PRICE	1	Less than 8 nucleotides in an oligo pool of Yersinia enterocolitica O3F4 antigens within Y10 with the following genes deleted from the chromosome: rfaA, rfaB, rfaC	1038E1	\$1.00	TOTAL:			\$1.00
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TOTAL:			\$1.00											
The Export Administration Regulations require you to take the following actions when reporting under the authority of this license.														
<p>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.</p>														
<p>CONDITIONS:</p> <p>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>														
Page 1 of 2														

Export License
 D1642284
 Validated: December 22, 2015
 Expires: December 31, 2019

 **UNITED STATES DEPARTMENT OF COMMERCE**
BUREAU OF INDUSTRY AND SECURITY
 WASHINGTON, D.C. 20530

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 4005, 1401 Constitution Ave, NW, Washington, D.C. 20530. This office may be contacted by telephone at (202) 452-2355 or facsimile at (202) 482-2971.

II. This office may be contacted by telephone at (202) 482-2355 or facsimile at (202) 482-2971.

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 must specific requirements may enter the laboratory. E. A biohazard sign must be posted on the entrance to the laboratory when etiologic agents are in use. Appropriate information to be posted includes the agent in use, the biosafety level, the required immunizations, the investigation name and laboratory number, any special 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 specimens 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 \(IATA\)](http://www.iata.org) 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.

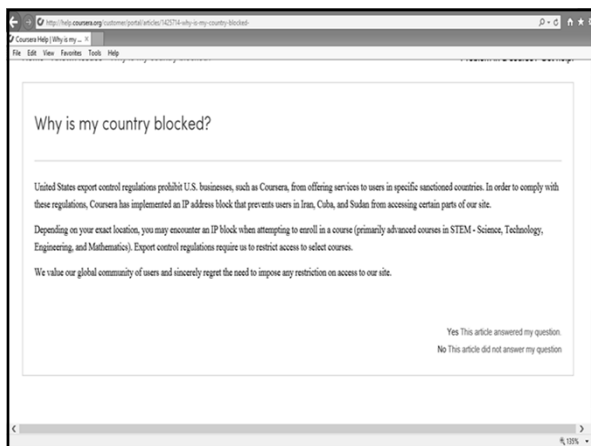
Larger number of SDN's
ALBANIA, BANGLADESH, BOSNIA, CAMBODIA, COLUMBIA, GHANA, KOSOVO, KUWAIT, MEXICO, PAKISTAN AND PALESTINE.

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.



Why is my country blocked?

United States export control regulations prohibit U.S. businesses, such as Coursera, from offering services to users in specific sanctioned countries. In order to comply with these regulations, Coursera has implemented an IP address block that prevents users in Iran, Cuba, and Sudan from accessing certain parts of our site.


Depending on your exact location, you may encounter an IP block when attempting to enroll in a course (primarily advanced courses in STEM - Science, Technology, Engineering, and Mathematics). Export control regulations require us to restrict access to select courses.

We value our global community of users and sincerely regret the need to impose any restriction on access to our site.

Yes This article answered my question
No This article did not answer my question

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.



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)
