

## Mass General Brigham Export Controls Travel Guidance for Researchers

February 2023

### **Introduction**

This *Travel Guidance* has been developed to provide Mass General Brigham (MGB) researchers with information they should consider before traveling abroad as part of their research duties. While international travel and collaboration are an exciting part of research, they are subject to unique regulatory requirements referred to as ‘export controls.’

You may be thinking ‘export controls’ do not apply to you because you don’t export anything. Upon closer scrutiny, this may not be the case.

- You do ‘export’ when you ship items, software, or information internationally or travel with these items outside the US.
- You may ‘export’ when you perform research at MGB or collaborate with someone from outside the US.

For the definitive MGB statement on export controls, see the [Mass General Brigham Export Controls Policy](#).

Below are common questions about Export Controls.

### **What are export controls?**

Export controls are federal laws and regulations that control the export of strategically important products, services, and technologies to foreign persons and nations. Items carried across US borders are considered ‘exports.’ If restrictions apply, you may need to obtain a license from the appropriate federal agency (e.g., Department of Commerce or Department of State) before bringing the item or information outside of the country.

Export controls also include the transfer of technology or “know how” to a foreign national, whether it occurs in the United States or abroad. This is known as a “deemed” export from the United States to the home country of the foreign national.

### **How do I find out whether an export controls license is required for the country I plan to visit? If a license is required, are there restrictions on what I can bring with me?**

License determination depends on a variety of factors, for example, whether the country you will be visiting is subject to sanctions or a trade embargo; the type of item or information leaving the country (i.e., exported); and the person or entity that will ultimately use the export. Obtaining a license can take several weeks or months.

The US Treasury Office of Foreign Asset Control (OFAC) publishes a list of sanctioned countries and what the sanction or embargo actually entails on its [web site](#).

Travel to embargoed or sanctioned countries will most likely require a license. Countries currently subject to OFAC sanctions include the Balkans, Belarus, Burundi, Central African Republic, Darfur, Democratic Republic of the Congo, Iran, Iraq, Lebanon, Libya, North Korea, Russia, Somalia, Sudan, South Sudan, Syria, Ukraine, Venezuela, Yemen, and Zimbabwe.

If you are planning to travel to these countries or have questions about the status of a country you intend to visit, you should contact your Research Compliance Office prior to making your travel plans. With the exception of Cuba, travel to embargoed or sanctioned countries is generally permitted, but the items you carry with you (e.g., laptop, smart phone) and the financial transaction related to travel may be restricted.

### **What about travel to countries not subject to sanctions or a trade embargo? Can I bring my laptop? What about other electronic devices?**

In most situations, you will not need to obtain a license to take your standard, commercially available laptop computer, mobile computing device or data storage device with you, and you probably will not need to take any special actions to comply with export regulations.

If you will be temporarily traveling outside of the US to a non-sanctioned country, you may take 'tools of the trade' with you for activities related to your travel. Laptops and the devices noted above generally fall into this category. The traveler (or designee) must ensure that the computer and software:

- Are reasonable and necessary for the purpose of use,
- Remain under their effective control (carried with them or locked in a secure safe) at all times, and
- Are returned to the US no longer than one year from time of export.

Certain high-performance computers and associated software may be restricted. If you will be bringing a non-standard computing device to a foreign country, contact your hospital's Research Compliance Office before traveling.

### **Can I bring encrypted devices?**

Any item that includes encryption technology is considered an "encryption item." This includes medical devices, communication devices, and more – not just computers and smart phones. Mass market encryption software is usually exempt from restrictions. If you have encryption software that is not readily available on the commercial market, you should consult your Research Compliance Office before leaving the country.

No encryption software or data is allowed in or out of Cuba, Iran, North Korea, Sudan, and Syria. When traveling to these countries, you should consult your Research Compliance Office before leaving the country.

### **Can I share research data and information with foreign colleagues?**

In most instances sharing information with foreign colleagues in their country or at international conferences is not subject to export control regulations as long as the information being shared falls into the category of fundamental research and is one of the following:

- Published or ordinarily intended for publication,
- Publicly available, or
- In the public domain.

Data that identifies a specific person, a research subject or patient, should not be exported without a formal agreement with the end-user or consent for disclosure from the subject. Contact your IRB regarding identifiable research data and your hospital's Privacy Office for non-research data.

### **Can I bring medical supplies with me?**

Traveling with medical supplies (e.g., gauze, tape, bandages, etc.) which you intend to donate at your destination does not usually require a license. For all destinations you must keep a record of the items you are donating, including who the donation is intended to benefit and the source of funding for the donated items. You may not charge a fee for the items.

Every country has its own import requirements which may include a fee. You should work with your contacts at your destination to determine what must be done to import items. It is acceptable, but not required by MGB, for the beneficiary to pay import fees.

### **Can I bring pharmaceutical products, devices and vaccines?**

We strongly recommend that any medications, except those intended for personal use, or vaccines be shipped via commercial carrier. You should work with the intended recipient to determine whether country-specific import requirements exist.

FDA-approved drugs and devices may be exported from the US but may require FDA certification that the drug or device meets FDA requirements for sale and use in the US. Usually, this is handled by the pharmaceutical company exporting the item; however, if you are asked for an FDA Export Certification, contact your hospital's Research Compliance Office.

The FDA also regulates export of investigational human drugs, biological products, medical devices, and animal drugs that have not yet been approved for sale in the US. Drugs, biologics, and medical devices that have been banned from sale in the US are also regulated when exported to a foreign country. There are mandatory FDA labeling, notification, and approval requirements. You may also be required to present certification of exportability from the FDA. Contact your Research Compliance Office for assistance.

Most vaccines are not restricted by Export Control Regulations; however, FDA-approved vaccines against pathogens or toxins that are specifically controlled by the Department of Commerce may require a license for export to certain destinations. In these situations, you should contact your hospital's Research Compliance Office for review.

### **Can I bring biological materials, specimens, and chemicals with me?**

We strongly recommend that these items be shipped via commercial carrier rather than transported with the traveler. There are many practical reasons for shipping instead of hand-carrying, including risk of damage to checked baggage and heightened scrutiny at security checkpoints for carry-on items. For complex cases, a shipping agent or customs agent may expedite the export of items from the US and entry into country of destination.

For more information contact:

- The Ragon Institute, 65 Landsdowne St., and 38 Sidney St: [Jessica Healey](#)
- BWH and MEE: [Kathy Joseph](#)
- MGH and McLean: [Anne Sallee](#)

A Material Transfer Agreement (MTA) is required when materials are transferred internationally. Requests for MTAs are made through the Agreements Module in [Insight 4.0](#). To start the MTA process, please review the [Guide to Get Started; Request a New Agreement](#). MGB Innovation's [Transactional Affairs Group \(TAG\)](#) can assist with these agreements.

### **Can I bring human specimens?**

Human specimens, including blood and tissue, are not typically restricted by export controls unless they contain a pathogen. If the specimens you are transferring are part of an IRB-approved protocol, you should make sure exporting the samples is consistent with the approved protocol and informed consent document. Again, we strongly recommend you use a commercial carrier to ship the specimens rather than transport them with the traveler.

### **Can I bring animals, tissue samples, cell lines and other non-human specimens?**

Like human specimens, animal specimens are restricted by export controls if they contain a pathogen. Most animal exports will require IACUC approval, as well as documentation from veterinary staff that the animals are healthy and safe for transfer.

- MGH: [Refer to the Center for Comparative Medicine's Exporting Animals Guidance](#)
- BWH: Refer to the [Center for Comparative Medicine's Animal Facility Guidance and Regulatory Information for Exporting Animals](#)

A Material Transfer Agreement (MTA) is required when materials are transferred internationally. Contact [MGB Innovation](#) to begin this process.

Finally, there may be restrictions placed on animals, tissue samples, cell lines, or other non-human specimens by the destination country. You should communicate with the end-user of these items to ensure all local requirements are met before shipping.

### **Can I bring pathogens, toxins and related genetic elements?**

Export control regulations restrict the export of certain human, animal, and plant pathogens. A list of these items can be found under IC351, IC352 and IC354 respectively within Category I of [the Commerce Control List \(Materials, Chemicals, Micro-organisms and Toxins\)](#).

Genetic elements associated with these pathogens on these lists may also be restricted even if they have been placed in non-restricted organisms. Pathogens restricted under export controls regulations tend to be highly infectious, have a high rate of morbidity or mortality, or tend not to be common infectious agents worldwide. If you work with any pathogens on these lists and wish to share material with foreign collaborators, you should contact your Research Compliance Office.

### **What are financial transactions? Do financial transactions have special requirements?**

Financial transactions refer to any exchange of items of value and may include money received as payment, such as an honorarium for speaking at a conference or plane tickets received for teaching a training class. Transactions may also include payment for research or medical services in a foreign country. Most personal financial transactions necessary to secure transportation or arrange for a hotel are permitted without restrictions.

As a general rule, if the transaction involves an OFAC sanctioned country, contact your Research Compliance Office to determine if a license is needed.

The US Treasury's Office of Foreign Asset Control restricts financial transactions between US individuals/entities and blocked foreign nationals/entities. Check the consolidated export screening list and the US Treasury SDN list to determine if an individual or entity party to a transaction is restricted under these regulations.

Individuals participating in financial transactions overseas should be aware that they may be subject to the Foreign Corrupt Practices Act (FCPA). Interactions with government officials can be complex and making certain payments in order to further your business in the country could violate the FCPA. Contact your hospital's Research Compliance Office if you have questions or concerns about this matter.

### **What else should I know when traveling?**

[TravelSafe](#) is a travel information and assistance program that was created to help MGB travelers with a single point of contact in an emergency and to provide important travel information while traveling domestically or internationally on business related travel.

### **Export Controls Contacts**

- BWH Research Compliance | [Kelly Barrett](#)
- MEE Research Compliance | [MGB Research Compliance \(Interim\)](#)
- MGH Research Compliance | [Kele Piper](#)
- Spaulding Research Compliance | [Monica Baggio Tormey](#)
- McLean Research Compliance | [Kimberlee Roselando](#)
- MGB Research Compliance | [Ryan Schlimgen](#)