



Mass General Brigham

Export Controls Refresher Training

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Why Are We Here?

MGB Export Controls Policy

All involved with research must conduct their activities in accordance with US laws and regulations, including compliance with those pertaining to Export Controls.

It is the expectation that anyone who has a role in negotiating or administering MGB international research, licensing, or advisory services agreements has a working knowledge of basic federal export controls requirements, and that they take responsibility for compliance.



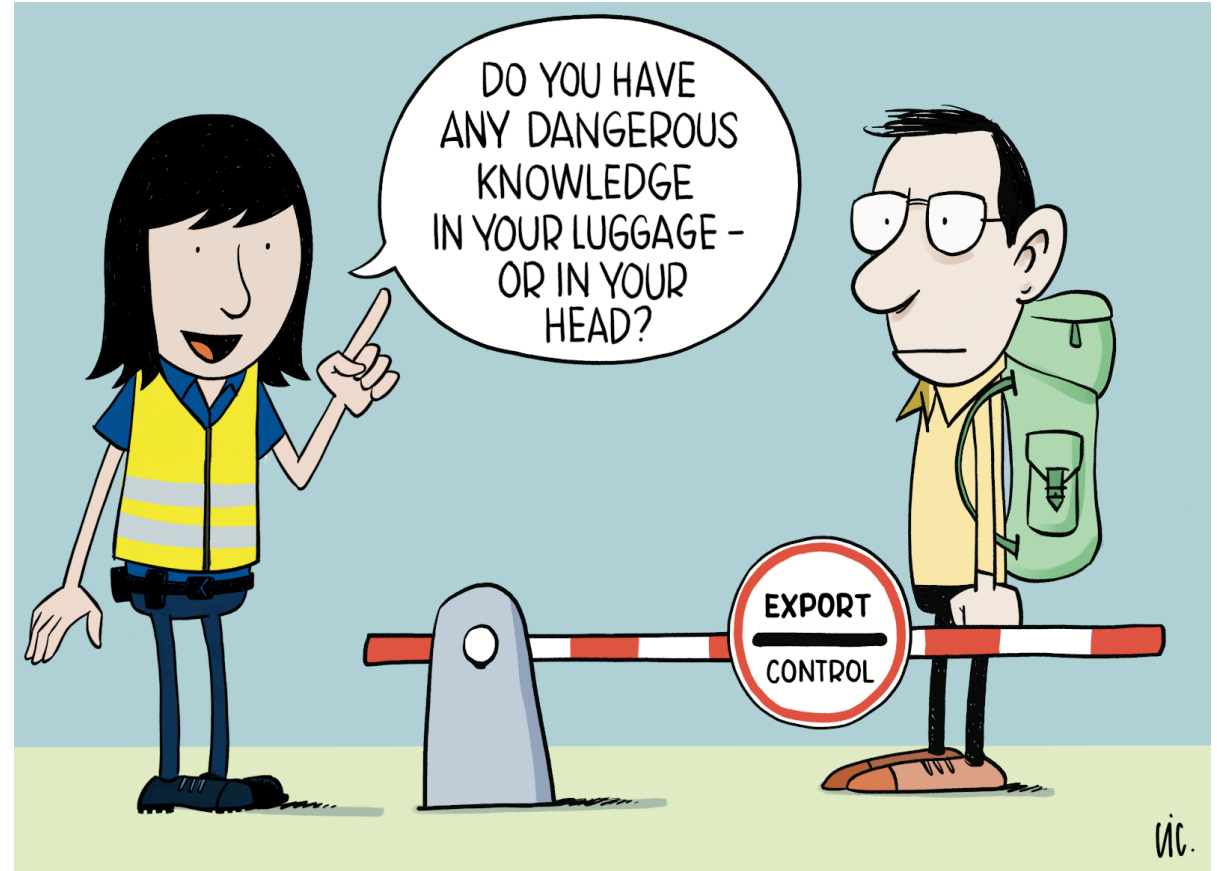
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Exports Are...

... Any oral, written, electronic or visual disclosure, or shipment, transfer or transmission of any commodity, technology (including info., technical data, assistance), or software to:

- **Anyone outside of the US**
(including US citizens)
- **Any non-US entity or individual**
(including those physically located in the US)



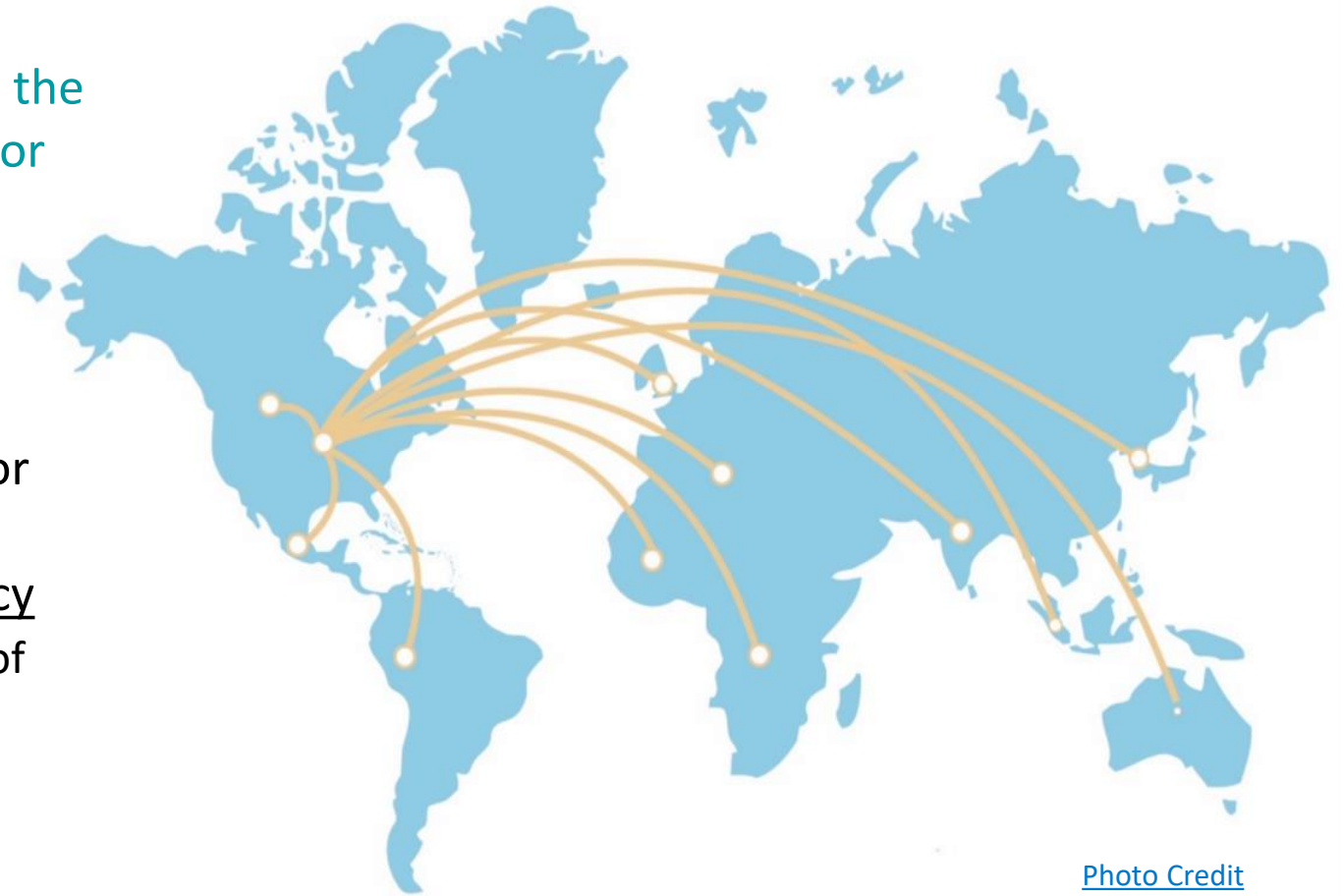
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Export Controls Laws...

...Are a set of federal regulations that regulate the movement of items, information, technology, or financial support, of US origin, to foreign individuals or entities.

...Limit the export of items that have military or civilian applications and may pose a risk to US national security, and support US Foreign Policy goals and objectives (i.e., prevent proliferations of weapons of mass destruction vis-à-vis terrorism).



[Photo Credit](#)



MGB Activities with Export Controls Implications



Restricted
Sponsored Research



Research Conducted
Abroad



International
Collaborations



International Travel



International
Shipping



Foreign Visitors &
Scholars



Employing Foreign
Nationals



Procurement and
Purchasing



MGB Deemed Exports (Transfer in the US to a Foreign National or Entity)



Tours of Lab Spaces



Involvement in Research



Discussions or Lectures



Hosting Observers or Other Visitors in MGB Research Spaces



Some Items Require a License to Export

Export Examples

- Sending biological pathogens to a foreign lab (MTA)
- Lending controlled equipment to a foreign site

Deemed Export Examples (Physically located in the US)

- Sharing information with foreign students or professors from embargoed/restricted countries
- Hosting foreign scientists from embargoed/restricted countries
- Tours of lab space from embargoed/restricted countries



Controlled Technologies May Require a License

If MGB Research involves **Controlled Technologies**, a license may be required before:

1. Allowing certain foreign researchers in the US to participate in the research
2. Sharing results with foreign persons
3. Providing training and other services to foreign persons
4. Sending equipment or software outside of the US



Export Controls Regulations and Regulators



Office of Foreign Assets Control (OFAC)

- Sanctioned Countries
- Embargoes
- Bad Actors



Export Administration Regulation (EAR)

- Commerce Control List (CCL)
- Dual Use Items

(i.e., commercial intent, but can have military applications)



International Traffic in Arms Regulations (ITAR)

- Defense & Satellite Items

(i.e., Technology designed to cause casualties or defend against biological attacks)



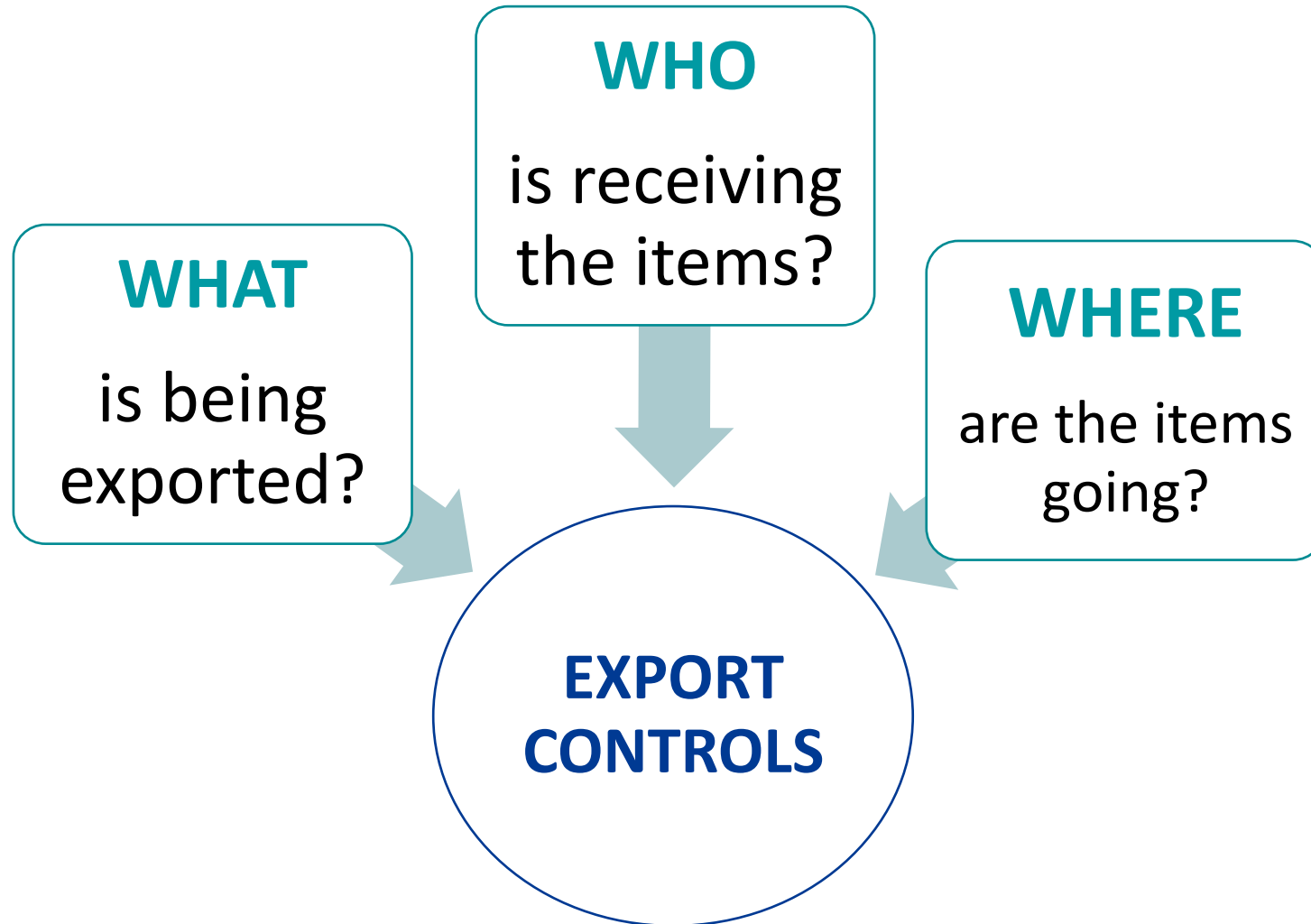
Customs and Border Control (CBP)

- Foreign Nationals entering the USA

(i.e., Deemed Exports)



Three Criteria when Considering Export Controls



The Where - MGB Countries of Concern

OFAC - SANCTIONS & EMBARGOES

Targets:

- Finance
- Trade
- Services

Key Takeaway: Payments may be restricted based on country of origin.

Remember:

Check with the [Institutional Export Control Officer](#) to make sure that we can pay vendors.

EAR - COMMERCE CONTROL LIST (CCL)

Targets:

- National Security Materials & Technology (D1)
- Chemical/ Biological Materials & Technology (D3)

Key Takeaway: Sending materials to vendors outside of the US/to a country of concern may be restricted by the CCL.

Remember:

Determine which materials or information a vendor needs from MGB to perform their service.



List of Countries of Concern

- Afghanistan
- Armenia
- Azerbaijan
- Bahrain
- Belarus
- Burma
- Cambodia
- China
- Cuba
- Egypt
- Georgia
- Iran
- Iraq
- Israel
- Jordan
- Kazakhstan
- North Korea
- Kuwait
- Kyrgyzstan
- Laos
- Lebanon
- Libya
- Macau
- Moldova
- Mongolia
- Oman
- Pakistan
- Qatar
- Russia
- Saudi Arabia
- Syria
- Taiwan
- Tajikistan
- Turkmenistan
- United Arab Emirates
- Uzbekistan
- Venezuela
- Vietnam
- Yemen



The What - Materials and Technologies

Commerce Control List (CCL) – 9 Sections:

1. Materials, Chemicals, Microorganisms, & Toxins
2. Materials Processing
3. Electronics
4. Computers
5. Telecommunications & Information Security
6. Sensors & Lasers
7. Navigation & Avionics
8. Marine
9. Aerospace & Propulsion

Inclusion on the CCL does not necessarily mean restrictions will apply because restrictions are also based on the export's *destination* and the *expected end-user*.

US Munitions List:

- **Munitions** are Goods & technology *designed* to cause or increase human casualties or defend against biological or chemical attacks in *military settings*.
- Restricts the export of items and technology that have **direct military applications**.

Very rarely, if ever, do MGB Institutions engage in the export of these items.



What does MGB Export?

Items that may have Export Control Issues

Physical Objects

- Lasers
- MRI machines

Biological Agents

- Shiga Toxin, Tetrodotoxin, Brucella abortus, Salmonella Typhi, Vesicular Stomatitis Virus (VSV)
- Organisms or vectors that contain genes from these agents

Technical Data/Information

- Manuals for machines
- Unpublished sequences for genes in biological agents

Software Code & Computer Code that runs Autonomous Sensors

- Encryption software

Money In/Out

Payments



EAR99 - Medical & Research Items Exported by MGB

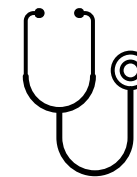
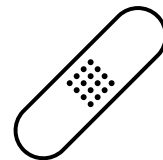
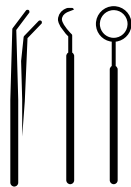
EAR99-classified items are products, services, and technologies that are not specifically export-controlled.

- **Most biomedical materials and technology & medical and surgical products are classified as EAR99.**

List of Medical Devices Classified as EAR99:

<https://www.bis.doc.gov/index.php/documents/product-guidance/711-bis-list-of-ear99-medical-devices/file>

- Falls under US Dept of Commerce's jurisdiction and are not listed on the Commerce Control List (CCL).
- Items classified as EAR99 do not require a license to export unless it is to an embargoed country or end-user of concern. *[Note: One-year specific license applications must be submitted to OFAC for re/export to Iran and Sudan.]*



Exemptions for Materials and Technology

Public Domain Exemption = Information already published and generally available to the public. This includes published research articles, scientific books, and patents.

Education Exemption = Information intended for students, including foreign nationals, concerning general scientific, mathematical or engineering principles commonly taught in schools, colleges or universities

Fundamental Research Exemption (FRE) = Fundamental Research is defined as basic and applied research in science and engineering which ordinarily are published and shared broadly within the scientific community.



Fundamental Research Exemption

- Fundamental Research is science and engineering **research that is ordinarily published and shared broadly** within the scientific community.
- Research **will NOT** be considered fundamental research if:
 - There are restrictions on the publication of scientific and technical information resulting from the project.
 - There are restrictions (such as foreign national participation), due to proprietary or national security reasons.

MGB rarely engages in research that doesn't qualify as Fundamental Research.

Please notify your Export Control Officer if your project may not meet the FRE criteria.
(Historically, this has included grants and contracts from the Department of Defense or NASA).



Export Controls Issues – Where We See Them

Export Controls language issues can be found throughout any Agreement - *not* just in the Export Controls Section.

Examples of contract language to avoid that could invalidate FRE:

- “Final scientific review prior to publication”
- “Approval prior to publication”
- “No publication allowed”

Remember: Any review for proprietary information should be *reasonable* and *as short as possible*.



Compliance Responsibility

Both parties need to follow all applicable laws and regulations:

- MGB will follow US Laws and Regulations
- Laws and Regulations of the other party's home country

Identify who is responsible for performing export control screens and applying for licenses:

- **Other Party Responsibility** – Typically, MGB contracts and agreements have placed all responsibility on the other party.
- **Mutual Responsibility** – Is acceptable; MGB will screen and apply for licenses for *our* materials and expect the other party to do the same for theirs.
- **MGB Responsibility** – Generally not acceptable; MGB does not have the information nor resources to perform this service for other parties.



Additional Export Controls Considerations

There may be other requirements and regulations when working with international partners such as:

1. Materials of US-origin exported abroad may be subject to [Import Laws and Regulations of the receiving country](#).
 - Remember to consider [countries through which the materials may travel through](#) to get to their destination as compliance with both import and export regulations may be required.
2. Importing materials into the US as part of an agreement may have to comply with [US Import Laws and Regulations](#).



[Photo Credit](#)



Cost of Non-Compliance

REMEMBER

Regulators expect that all members of an institution understand export controls requirements and take responsibility for compliance.

OFAC, EAR, & ITAR carry civil and criminal penalties:

- The person initiating a transaction is responsible for identifying issues.
- Range of Penalties: Up to \$1M in fines; Up to 10 years imprisonment.



[Photo Credit](#)



Key Takeaways – Export Controls

INCLUDES

Any item* of **US origin** that is shipped, transferred, or undergoes transmission to anyone (*including US citizens*) outside of the US and any non-US entity or foreign national located in the US.

* **Items:** Goods, Technology, Information, Software Code, or any other Commodity

EXCLUDES

- Items in the public domain
- Patents or Patent Applications
- Non-Technical Publications
 - Maps
 - Children's Books

*Contact the [Institutional Export Control Officer](#) if you identify an **OFAC Sanctioned Country** or a **Restricted Item** in a contract or service agreement so that they can conduct an Export Controls Risk Assessment.*



MGB Export Controls Resources

- [MGB Export Controls Policy](#)
- [Research Navigator](#)
- [Additional Training](#)
 - Federal Export Controls Regulations and Compliance Requirements
 - **Special Topics:**
 - Compliance with Section 889, 2019 Federal Defense Authorization Act (FDAA), Covered Technologies
 - Sponsored Research, Technology Transfer, & Licensing Issues
 - Special Topic: International Advisory Services
- [Institutional Export Control Officers](#)

Export Controls Review Checklist



Central Contracting Checklist - Export Control Review
December 2022

Countries designated controlled for national security or Chemical & Biological purposes are found in [Country Screen D.1/3](#) and include the following restricted countries:

| | | |
|-------------|-------------|----------------------|
| Afghanistan | Israel | Pakistan |
| Armenia | Jordan | Qatar |
| Azerbaijan | Kazakhstan | Russia |
| Bahrain | North Korea | Saudi Arabia |
| Belarus | Kuwait | Syria |
| Burma | Kyrgyzstan | Taiwan |
| Cambodia | Laos | Tajikistan |
| China | Lebanon | Turkmenistan |
| Cuba | Libya | United Arab Emirates |
| Egypt | Macau | Uzbekistan |
| Georgia | Moldova | Venezuela |
| Iran | Mongolia | Vietnam |
| Iraq | Oman | Yemen |

| Question | Consideration | Action |
|---|--|--|
| Who are the Parties? | Is one of the parties in the proposed project from one of the countries listed above? | If a Party is from one of the countries above refer to Research Compliance |
| Will MGB perform work directly on the ground, in country? | Will MGB perform any of the work, travel to, or directly recruit subjects from a foreign country? Or will on the groundwork be performed by a local party? | If MGB will engage in ANY direct on the ground activity refer to research compliance. Otherwise if local partner is engaging in on the ground activity only refer to Research Compliance if partner is from an above-named country. |
| Will MGB transfer material or information to collaborators in country? | Will MGB send material or information (data) to another country? Is this material or data proprietary or commercial? Will it be shipped to one of the countries listed above? | If the material or information known to be controlled under the CCL or ITAR refer to Research Compliance If Material is being sent to a country listed above send to Research Compliance. |
| Does the contract or agreement contain Export Control terms that differ from the standard MGB export control terms? | Do the terms restrict who can work on a project based on nationality? Do the terms require additional compliance checks? Do the terms require MGB to identify any export control restricted items, information or technology? Do the terms place restrictions on publication? | Refer to Research Compliance |



Institutional Contacts

Brigham and Women's Hospital (BWH)

- [Kelly Barrett](#) – Research Operations Manager
- [Brendan Garvin](#) – Research Operations Manager
- [Kenneth Cruz-Sanchez](#) – Research Operations Associate

Massachusetts General Hospital (MGH)

- [Kelé Piper](#) – Director of Research Compliance
- [Mirabella Daguerra](#) – Sr. Research Compliance Specialist

McLean Hospital (McL)

- [Kim Roselando](#) – Sr. Research Compliance Specialist

Spaulding Rehabilitation Hospital (SRH)

- [Monica Baggio Tormey](#) – Chief Compliance & Privacy Officer

Mass General Brigham (MGB) & Mass Eye and Ear (MEE)

- [Ryan Schlimgen](#) – Sr. Director of Biosafety & Export Control Officer
- [Claire Moretti](#) – Biosafety & Export Controls Program Manager





Mass General Brigham