Export Control Oversight Policy

Approval Date: December 17, 2021

POLICY

It is the policy of the Icahn School of Medicine at Mount Sinai ("ISMMS") to comply with all U.S. trade control laws, including export control, economic sanctions, anti-boycott laws and regulations, customs and import laws and regulations, and any other laws and regulations that regulate international activities, that apply to its activities (collectively "Export Control Laws"). These laws and regulations restrict or prohibit a range of activities, including the export, reexport, import, or transfer of certain items, materials, software, and information from or into the United States. They also restrict the release of certain export-controlled information or technology verbally, in writing, or in any other way to Foreign Persons in the United States or abroad without authorization from the U.S. Government. While there are exceptions to these restrictions and regulations, such as the Fundamental Research Exclusion ("FRE"), we must ensure that we all are aware of and follow the applicable rules.

PURPOSE

The purpose of this policy is to provide guidance to the ISMMS community on Export Control Laws, and how they should be managed as they relate to the work undertaken at ISMMS to promote compliance.

APPLICABILITY

This policy applies to all ISMMS employees, faculty, researchers, fellows, visiting scientists, students, volunteers, contractors, third parties, staff, and any affiliated party conducting research in ISMMS facilities or with ISMMS resources (collectively, “ISMMS Parties”) or otherwise engaged in international activities. ISMMS includes any entity, group, department, division, or laboratory of the Icahn School of Medicine at Mount Sinai.

It is the responsibility of ISMMS Parties to be familiar with this policy and prevent any transactions contrary to this policy. Violations of Export Control Laws could subject ISMMS and/or individuals responsible for the violation to severe criminal and/or civil penalties, including fines and possible imprisonment. All ISMMS Parties are expected to read and comply with this policy.

For any questions relating to this policy or Export Control Laws, please contact the Export Control Officer (see below). The Export Control Officer is the individual at ISMMS who assumes the responsibility for ISMMS compliance with relevant export control regulations. This includes adhering to recordkeeping requirements and documenting ISMMS’s commitment to, and compliance with, Export Control Laws and related regulations generally.

This policy does not include a discussion of export restrictions administered by the Department of Energy, the Nuclear Regulatory Commission, and the Food and Drug Administration. This policy also does not discuss non-U.S. international trade laws and regulations that may be applicable to certain ISMMS activities. Any research subject to these regulations will be addressed on a case-by-case basis. For any questions on these matters, please contact the Export Control Officer.
BACKGROUND ON EXPORT CONTROL LAWS

1. Overview - Exports

There are three primary sets of regulations restricting the transfer of goods, technology, and information to persons and entities outside of the United States, as well as other activities and services involving such persons and entities: the Export Administration Regulations (“EAR”), the International Traffic in Arms Regulations (“ITAR”), and the regulations administered by the Office of Foreign Assets Control (“OFAC”). These regulations serve several purposes: to restrict exports of goods, technology, and information that could contribute to the military potential of U.S. adversaries; to prevent proliferation of weapons of mass destruction; to advance U.S. foreign policy goals; and to protect the U.S. economy and promote trade goals. Also discussed below are the U.S. antiboycott laws, which prohibit U.S. persons and their affiliates from participating in the Arab League boycott against Israel.

Although academic, non-commercial research normally is conducted openly and most research activities are not subject to export control regulations (e.g., Fundamental Research), there are certain conditions under which the export of materials, equipment, software, or technology either is prohibited or requires a license (such items are commonly referred to as “controlled” items). Examples of “controlled” items include materials such as certain precursor chemicals, human or animal viruses (e.g., Newcastle Disease Virus (“NDV”)), toxins, bacteria, plant pathogens, genetic elements, and genetically modified organisms of controlled pathogens and toxins (e.g., vaccine seeds containing an intact gene of NDV), and equipment/materials commonly used in laboratories (e.g., batch mixers, centrifugal separators, protective and containment equipment). Vaccines that have been approved by the U.S. Food and Drug Administration either to be marketed as clinical or medical products or for use as an “Investigational New Drug” are controlled at a low level and only require licenses for sanctioned countries.

Certain “controlled” technology, which includes certain technical and scientific data, requires an export license unless it meets the test that the associated research is intended for publication or otherwise in the public domain under the FRE. For instance, unpublished, proprietary technical data or documents related to a controlled pathogen, such as NDV, are highly controlled and would require authorization for export or release to most foreign destinations or Foreign Persons. Publication restrictions (other than a limited review for patent protection or for the removal of a sponsor’s proprietary information) or limitations on access or dissemination of research results to Foreign Persons removes the information from the public domain and would invalidate the FRE, if applicable, which is discussed in more detail below. The majority of exports associated with academic research – including Deemed Exports – do not require government export licenses because the FRE applies. In some situations, however, a license may be required. In cases where a license is required, ISMMS will facilitate the application for such license and ensure compliance with all necessary regulations.

2. Fundamental Research Exclusion and the “Public Domain” Exclusion

The FRE under the EAR and ITAR broadly exempts most academic, non-commercial research from export controls when certain conditions are met. FRE may apply to ISMMS activities that involve research in science and engineering where the resulting information is ordinarily published and shared broadly in the scientific community. Such research is 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. With certain limited exceptions, research does not qualify as FRE if publication restrictions or delays exist. It is ISMMS policy that research results be publishable. In extremely rare instances, ISMMS may grant exceptions to this policy. Requests for exceptions to this policy will be made, in writing, and submitted to either the Export Control Officer, Grants and Contracts Office (“GCO”) or Mount Sinai Innovation Partners (“MSIP”). Requests that merit consideration will be forwarded to the Dean ISMMS who will decide or refer to a designee. If an exception is granted, it must be registered with the Export Control Officer who will impose safeguards to ensure compliance with all Export Control Laws.

ICAHN SCHOOL OF MEDICINE AT MOUNT SINAI
EXPORT CONTROL OVERSIGHT POLICY
Page 2 of 10
The criteria for the FRE under the ITAR and EAR are different, with the ITAR definition more restrictive and limited to activity on-campus and in the United States only. The FRE must be assessed on a case-by-case basis.

Note that the FRE does not apply to physical shipments or transfers of equipment, materials, hardware, software, or other items overseas and such exports must still be analyzed to determine whether controls will apply. In addition, note that the FRE does not apply to any proprietary or confidential “input” technology or information received from a research sponsor or supplier that ISMMS agrees not to share or publish. If ISMMS receives any proprietary or confidential technology or information from an entity sponsoring research at ISMMS or from a supplier (“input data”), ISMMS will need to determine the export classification of such input data in order to assess whether an export license is required prior to exporting or releasing the input data to Foreign Persons (including Foreign Persons working at ISMMS).

The “public domain” exclusion under the EAR and ITAR allows both Deemed Exports as well as exports from the U.S. of information and software that is already published, with the exception of certain encryption software. While the EAR and the ITAR define “publish” somewhat differently, essentially under both regulatory regimes information becomes published when it is generally accessible to the interested public in any form such as:

- Readily available at libraries open to the public or at university libraries;
- In patents and published patent applications;
- Released at an open conference, meeting, seminar, trade show, or other open gathering; or
- Published in periodicals, books, print, electronic, or other media available for general distribution (including websites that provide free uncontrolled access) or for distribution to a community of persons interested in the subject matter, such as those in a scientific or engineering discipline, either free or at a price that does not exceed the cost of reproduction and distribution.

3. Export Administration Regulations

The Department of Commerce’s Bureau of Industry and Security (“BIS”) administers the EAR, which regulates the export, reexport, or transfer of commercial and “dual-use” items (items having both a military and commercial application). These items can include equipment, biologics, technologies (including software), and technical data that serve primarily civil uses.

An "export" is an actual shipment or transmission of services or any item, including information, technology, software, and data, out of the United States. How the transfer occurs does not matter in determining export license requirements. An item may be exported even if communicated visually, verbally, or electronically. “Technology” as defined in the EAR is specific information necessary for the “development”, “production”, or “use” of a product. The information takes the form of “technical data” or “technical assistance.”

A “Deemed Export” is an “export of” controlled technology or source code by a Foreign Person inside the United States, including by providing access to such controlled technology or source code to a Foreign Person.

A “reexport” is a transfer of U.S.-origin goods from a third country to another destination outside of the United States. A reexport could occur if an ISMMS department or division were to send a sample of a virus to an international partner, and the partner sent the sample to a third country.

Examples of activities that could result in “exports control oversight” include:

- Labs exporting samples of viruses and other pathogens, and genetic elements and genetically modified organisms that include such pathogens set forth in the EAR, the Australia Group’s “List of Human and Animal Pathogens and Toxins for Export Control,” and/or the APHIS/CDC “select
agents” list (e.g., the export of an NDV-based vaccine seed requires an export license to any country).

- Having any Foreign Person (including foreign students, post-doctoral researchers, or colleague) visit the areas at ISMMS in which export-controlled research is being conducted (which could be a Deemed Export).
- Having a Foreign Person work on a research project or in an ISMMS area involving access to export-controlled technology (e.g., a Foreign Person accessing third-party technical data related to the production of a controlled pathogen that is not eligible for the FRE, which would be a Deemed Export).
- E-mailing export-controlled information from a research project to a Foreign Person colleague or sponsor.
- Presenting export-controlled technology at a non-public conference or meeting.
- Providing export-controlled technical assistance or instruction to a Foreign Person either in the United States or abroad.

The Commerce Control List (“CCL”) is a part of the EAR and contains a list of hardware, software, and technologies that are subject to the EAR. Each item on the CCL is assigned an Export Control Classification Number (“ECCN”), which is either EAR99 (a “basket” category subject to the lowest level of control) or a five-digit alpha/numeric code for items identified on the CCL. The ECCN determines whether or not prior authorization from the U.S. Government is required to export an item to a particular destination. For example, items classified under ECCNs 4A994, 5A992, 5D992, and EAR99 are subject to a low level of control and generally can be exported to any destination, except to sanctioned countries or Restricted Parties.

Exports and reexports of items controlled under the EAR may be subject to export license requirements, depending upon the level of controls applicable to the item, the destination country, the identity of the parties, and the purposes for which the item is intended to be used. A number of license exceptions may be available under these regulations, depending upon the facts and circumstances of the particular transaction.

ISMMS activities may involve certain items controlled under the EAR, including but not limited to: certain precursor chemicals, viruses (both human and animal), toxins, bacteria, genetically modified organisms (“GMOs”), or genetic elements that contain or code for the genes of controlled pathogens or subunits of controlled toxins (including in some cases where the GMOs or genetic elements are not themselves pathogenic), plant pathogens, vaccines, and various equipment and materials. For example, a vaccine seed that contains at least one gene specific to NDV would be highly controlled under the EAR.

4. International Traffic in Arms Regulations

The U.S. Department of State Directorate of Defense Trade Controls (“DDTC”) implements and administers the ITAR. The ITAR control the export, reexport, temporary import, and brokering of defense articles, defense services, and defense-related technical data by imposing stringent restrictions on their export, reexport, temporary import, or brokering. Virtually all transactions subject to the ITAR require specific authorization from DDTC. Only very limited license exemptions are available under these regulations.

Items covered under ITAR are contained in the United States Munitions List (“USML”). Defense articles can include hardware or software that has been modified for military use or to military specifications, as well as related technical data. “Technical data” is defined under the ITAR as including (1) any information (classified or unclassified) required for the design, development, production, manufacture, assembly, operation, repair, testing, maintenance, or modification of defense articles as well as software directly related to defense articles; (2) any classified information relating to defense articles and defense services; and (3) software that is directly related to defense articles. Technical data can include information in the
form of blueprints, drawings, photographs, plans, instructions, and documentation. Technical data does not include basic marketing information on function or purpose or general system descriptions. The ITAR applies not only to U.S.-origin technical data but also to foreign-origin technical data that is brought into the United States.

All exports, reexports and other transactions involving defense articles, services and technical data must be consistent with the ITAR, and any enhancements or modifications of existing commercial products for military customers or for military applications must be immediately reported to the Export Control Officer.

5. Economic Sanctions Regulations

Economic sanctions regulations and programs are administered by the U.S. Department of the Treasury’s OFAC and apply to designated countries, entities, and individuals. The sanctions programs vary in nature (e.g., territorial or “list-based”) and scope (e.g., comprehensive or limited) and may restrict a broad range of exports, imports, and other transactions, including providing educational or research services, collaborating on research, signing contracts, travel to certain countries, and exporting materials, information, or other items to such countries (even for medical or humanitarian reasons). Depending on the sanctions program, restrictions can apply to U.S. entities, U.S. persons wherever located, non-U.S. affiliates of U.S. universities, and transactions involving U.S.-origin items, regardless of the nature of the product.

The U.S. Government currently maintains comprehensive territorial sanctions and export restrictions against Cuba, Iran, North Korea, Crimea, and Syria as well as more limited sanctions against individuals, entities, or economic sectors in certain countries, including Venezuela, China, Sudan, Ukraine/Russia, Myanmar, and other countries. A current list of OFAC sanctions programs is available at https://www.treasury.gov/resource-center/sanctions/programs/pages/programs.aspx. This list may change at any time.

ISMMS Parties should not conduct any transactions involving sanctioned countries or travel to such countries for business without consulting the Export Control Officer.

6. Restricted Parties

Restricted Parties lists are the various lists maintained by the U.S. and other governments of individuals and entities that are subject to economic sanctions or other trade restrictions. Transactions with Restricted Parties are prohibited or substantially restricted. These lists include but are not limited to the following:

- Entity List (BIS)
- Debarred List (DDTC)
- Denied Persons List (BIS)
- Foreign Sanctions Evaders List (OFAC)
- Non-Proliferation Sanctions (State Department)
- Sectoral Sanctions Identifications List (OFAC)
- Specially Designated Nationals List (OFAC)
- Unverified List (BIS)

The Restricted Parties lists are also subject to change at any time. It is ISMMS policy to not have any transactions with Restricted Parties without required prior authorization from the U.S. Government. Any activities involving a Restricted Party must be immediately raised with the Export Control Officer.

7. Customs Laws and Regulations
U.S. Customs and Border Protection (“CBP” or “Customs”) is the border enforcement agency charged with controlling, regulating, and facilitating the movement of carriers, people, and commodities between the United States and other nations, as well as other functions.

Every article entered into the United States, whether by mail, express courier (such as FedEx, DHL, and UPS), other commercial freight carrier or as luggage, unless subject to a specific exception, must be declared to CBP at the time of entry into the United States. Individuals must exercise “reasonable care” and “informed compliance” in the movement of any items into the United States (“importation”) and in determining the appropriate tariff classification, customs valuation, country of origin, marking/labeling, tariff rate, quantity and other information provided on import entry documents and must consistently and accurately report such information to CBP. Individuals must maintain entry documents and such other documents to support the tariff classification, customs valuation, country of origin, marking/labeling, quantity, and other information provided on entry documents for a period of not less than 5 years. Incorrect information provided on Customs entry documents, even if unintentional, can subject ISMMS to significant civil and even criminal penalties.

Additionally, under United States Customs law and regulations, every article of foreign (non-U.S.) origin must be labeled with its country of origin in such manner that the ultimate purchaser will be able to determine the country of origin of the item, unless specifically excepted by law.

8. Animal Plant Health Inspection Service (“APHIS”) Regulations

The Department of Agriculture’s APHIS plays a vital role in ensuring the free flow of agricultural trade by keeping U.S. agricultural industries free from pests and diseases and certifying that the millions of U.S. agricultural and food products shipped to markets abroad meet the importing countries’ entry requirements. APHIS makes sure that all imported agricultural products shipped to the United States from abroad meet the Agency’s entry requirements to exclude pests and diseases of agriculture. Certain plant, animal, and plant organisms, vectors, and agents are subject to APHIS import and/or export permits. Individuals should work with the Export Control Officer to ascertain the requirements for importing or exporting pathogens and other products.

9. Anti-Boycott Regulations

The anti-boycott laws and regulations administered by the U.S. Department of Commerce and the Internal Revenue Service generally prohibit U.S. entities, and entities controlled by them, from participating in unsanctioned boycotts. The anti-boycott laws were passed primarily to address the Arab League boycott of Israel. A boycott-related request may be oral or written and may or may not require you to take any specific action. In addition, there are reporting requirements under these laws.

The Export Control Officer is responsible for all such reporting requirements. If you think you have received a boycott request, or have any questions related to anti-boycott issues, please contact the Export Control Officer immediately and do not take any actions with regard to the request until you have received guidance from the Export Control Officer.

PROCEDURES AND TRAINING

All ISMMS Parties are responsible for ensuring their research, educational, and other business activities are conducted in compliance with Export Control Laws. Activities that may be subject to Export Control Laws include, but are not limited to, the following:

- Research & collaborations (whether in-person or remote);
- Technology transfer and licensing;
● International travel (including hand carrying baggage);
● International shipments (regardless of size or value);
● Foreign Persons at ISMMS (including researchers, staff, students, or visitors); and
● Purchasing, payments, and other financial transactions

ISMMS has or will implement procedures to address the activities listed above. In particular, the export, reexport, or transfer of all “controlled” materials, equipment, software, or technology to a third party be made pursuant to a Material Transfer Agreement (“MTA”) or Data Transfer Agreement (“DTA”). ISMMS Parties must also confirm that they do not hand carry controlled materials and equipment outside the United States without prior review and approval by the Export Control Officer.

All ISMMS parties who participate in activities involving “controlled” items must receive and document training on the basics of U.S. export control and sanctions compliance. Specialized training will be offered on an as-needed basis, as determined by the Export Control Advisory Committee.

The Export Control Officer will provide guidance and assistance with export control compliance and review activities that may be subject to Export Control Laws.

**RECORDKEEPING**

Export Control Laws contain specific recordkeeping requirements that must be satisfied. Individuals are responsible for maintaining either hard or electronic copies of all import and export documentation, including determinations that export rules do not apply or that a license exception is available to the project or situation, and entry documents and such other documents to support the tariff classification, customs valuation, country of origin, marking/labeling, quantity, and other information provided on entry documents, for a period of **not less than five years consistent with ISMMS’s document retention policy**. All responsible ISMMS Parties should have a clear documented understanding of who will retain the documents in a given situation.

**QUESTIONS AND REPORTING COMPLIANCE EXCEPTIONS**

If an ISMMS Party is not sure if a proposed activity is restricted, it is their responsibility to contact the Export Control Officer for assistance. ISMMS Parties are encouraged to contact the Export Control Officer as soon as possible when contemplating research that would involve interactions with an export-controlled item, or an entity or individual located in a sanctioned country.

If an ISMMS Party becomes aware of a violation of this policy or Export Control Laws, the ISMMS Party must immediately contact the Export Control Officer and immediately cease all related activities until further guidance is provided by the Export Control Officer.

Please contact the Export Control Officer with any questions concerning this policy:

Reginald W. Miller, DVM, DACLAM
Professor, Comparative Medicine & Surgery
Dean for Research Operations and Infrastructure
Senior Research Integrity Officer
Export Control Officer, MSHS
Email: reginald.miller@mssm.edu
Ph: 212.241.3006.
**GLOSSARY**

Animal Plant Health Inspection Service (“APHIS”) of the Department of Agriculture protects and promotes U.S. agricultural health (including both animal and plant well-being and disease prevention), regulates genetically engineered organisms, administers the Animal Welfare Act, and manages wildlife damage.

Anti-Boycott laws and regulations administered by the U.S. Department of Commerce and the Internal Revenue Service generally prohibit U.S. entities, and entities controlled by them, from participating in unsanctioned boycotts.

Bureau of Industry and Security (“BIS”) of the Department of Commerce administers the EAR.

Commerce Control List (“CCL”) is a part of the EAR and contains a list of hardware, software, and technologies that are subject to the EAR. Each item on the CCL is assigned an ECCN.

“Controlled” Items are materials, equipment, software, or technology for which the export, reexport, or transfer either is prohibited or requires a license.

Customs and Border Protection (“CBP” or “Customs”) is the U.S. border enforcement agency charged with controlling, regulating, and facilitating the movement of carriers, people, and commodities between the United States and other nations, as well as other functions.

Deemed Export is the concept that the release of controlled technology or source code to a Foreign Person inside the United States is an export of such items to the country of their nationality.

Directorate of Defense Trade Controls (“DDTC”) of the Department of State implements and administers the ITAR.

Export is an actual shipment or transmission of services or any item, including information, technology, software, and data, out of the United States. In addition, technical data and software source code shared with a Foreign Person inside of the United States is an export. How the transfer occurs does not matter in determining export license requirements. An item may be exported even if communicated visually, verbally, or electronically.

Export Administration Regulations (“EAR”) are administered by BIS and control the export of commercial and most dual-use items. “Dual-use” items are those items which have both commercial and military applications. These items can include equipment, technologies (including software), and technical data that serve primarily civil uses. Once it is determined that an item is EAR-controlled, the exporter must determine its ECCN. Exports and reexports of items controlled under the EAR may be subject to export license requirements, depending upon the level of controls applicable to the item, the destination country, the identity of the parties, and the purposes for which the item is intended to be used. A number of license exceptions may be available under these regulations, depending upon the facts and circumstances of the particular transaction.

Export Control Officer is the individual at ISMMS that will assume the responsibility for ISMMS compliance with relevant export control regulations. This includes adhering to recordkeeping requirements and documenting ISMMS’s commitment to, and compliance with, export control regulations generally.

Export Control Classification Number (“ECCN”) is the 5 digit alpha/numeric code for items identified on the CCL. The ECCN determines whether or not prior authorization from the U.S. Government is required to export an item to a particular destination. For example, vaccine seeds classified under 1C353 require a license to all destinations. Items classified under ECCNs 4A994, 5A992, or 5D992 are
subject to a low level of control and generally can be exported to any destination, except to sanctioned
countries or Restricted Parties.

Export Control Laws are all U.S. trade control laws, including export control, economic sanctions, anti-
boycott laws and regulations, customs and import laws and regulations, any other laws and regulations
that regulate international activities, that apply to ISMMS activities.

Foreign Person is any person who is not a U.S. Person (as defined below). A Foreign Person also
means any foreign corporation, business association, partnership, or any other entity or group that is
not incorporated to do business in the U.S. Foreign Persons may include international organizations,
foreign governments and any agency or subdivision of foreign governments such as consulates.

Fundamental Research is information arising during or resulting from research in science and
engineering where the resulting information is ordinarily published and shared broadly in the scientific
community, as distinguished from research the results of which are restricted for proprietary reasons or
specific U.S. Government access and dissemination controls. Fundamental Research and the resulting
information are generally exempt from export controls under the Fundamental Research Exclusion
below.

Fundamental Research Exclusion (“FRE”) under the EAR and ITAR broadly exempts most
academic, non-commercial research from export controls when certain conditions are met. The criteria
for the FRE under the ITAR and EAR are different, with the ITAR definition more restrictive and limited
to activity on-campus and in the United States only. The FRE must be assessed on a case-by-case
basis.

Information includes technical data such as models, formulae, engineering designs and specifications,
or technical assistance such as training or instruction.

Intermediate Consignee is the person that acts as an agent for a principal party in interest and takes
possession of the items for the purpose of effecting delivery of the items to the ultimate consignee. The
intermediate consignee may be a bank, forwarding agent, or other person who acts as an agent for a
principal party in interest.

International Traffic in Arms Regulations (“ITAR”) are administered by the DDTC under the AECA.
The ITAR control the export, reexport, temporary import and brokering of defense articles and defense
services. Items that are considered “inherently military in nature” or are otherwise on the USML fall
under these regulations. Virtually all transactions subject to the ITAR require specific authorization from
DDTC. Only very limited license exemptions are available under these regulations.

Icahn School of Medicine at Mount Sinai (“ISMMS”) includes any entity, group, or laboratory of
ISMMS.

ISMMS Parties includes all ISMMS employees, faculty, researchers, fellows, visiting scientists, students,
volunteers, contractors, third parties, staff, and any affiliated party conducting research in ISMMS facilities
or with ISMMS resources.

Office of Foreign Assets Control (“OFAC”) of the Department of the Treasury administers economic
sanctions programs that apply to designated countries, entities and individuals. The sanctions
programs vary in nature (e.g., territorial or “list-based”) and scope (e.g., comprehensive or limited) and
may restrict a broad range of exports, imports and other transactions, including providing educational or
research services. The U.S. Government currently maintains comprehensive territorial sanctions and
export restrictions against Cuba, Iran, North Korea, Crimea, and Syria as well as more limited sanctions
against individuals, entities, or economic sectors in certain countries, including Venezuela, China,
Ukraine/Russia, and other countries. A current list of OFAC sanctions programs is at
Public Domain Exclusion under the EAR and ITAR allows both Deemed Exports as well as exports from the U.S. of information and software that is already published, with the exception of certain encryption software.

Reexport is a transfer of U.S.-origin goods from a third country to another destination outside of the United States. A reexport could occur if an ISMMS laboratory were to send a sample of a virus to an international partner, and the partner sent the sample to a third country.

Restricted Parties Lists are the various lists maintained by the U.S. Government of individuals and entities that are subject to economic sanctions or other trade restrictions. Transactions with Restricted Parties are prohibited or substantially restricted.

Technical Data is defined under the ITAR as including (1) any information (classified or unclassified) required for the design, development, production, manufacture, assembly, operation, repair, testing, maintenance, or modification of defense articles as well as software directly related to defense articles; (2) any classified information relating to defense articles and defense services; and (3) software that is directly related to defense articles. Technical data can include information in the form of blueprints, drawings, photographs, plans, instructions, and documentation. Technical data does not include basic marketing information on function or purpose or general system descriptions. The ITAR apply not only to U.S.-origin technical data but also to foreign-origin technical data that is brought into the United States.

Technology as defined in the EAR is specific information necessary for the “development”, “production”, or “use” of a product. The information takes the form of “technical data” or “technical assistance”.

U.S. Person under export controls and sanctions laws and regulations includes a citizen or national of the United States, a lawful permanent resident alien of the United States (i.e., a green card holder), a U.S. refugee or a U.S. asylee. U.S. persons also include organizations and entities, such as universities, incorporated in the United States.

United States Munitions List ("USML") is a list of defense and space-related articles, services, and related technical data contained in the ITAR and designated as defense articles or defense services pursuant to the AECA.

**EFFECTIVE DATE AND REVISION DATE**

<table>
<thead>
<tr>
<th>Date</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>December 17, 2021</td>
<td>Approval Date</td>
</tr>
</tbody>
</table>