



Export Control Policy and Procedures

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I. PURPOSE

Investigators and other personnel at Memorial Sloan Kettering Cancer Center (MSK) engage in a broad range of innovative and important activities both in the United States and overseas. These activities sometimes include the sharing and development of research products, materials, hardware, software, (collectively "Items"), as well as research involving technology (which includes information, whether printed, inscribed on media, or communicated orally) (collectively "Information") that may be subject to US export control laws and regulations. The purpose of this policy is to clarify for the MSK community the essential aspects of the laws and regulations concerning export of certain Items and Information, and affirm the Institution's commitment to, and ensure compliance with, these complicated laws.

The US Departments of Commerce, State, and Treasury administer the primary controls on the export or transfer of certain Items and Information. The Department of Commerce regulates the export of Items and Information that have trade or national security implications, the Department of State regulates the export of Items and Information that have military applications or that relate to aerospace, and the Department of the Treasury enforces trade embargoes and sanctions against specific countries, entities, and individuals. In certain circumstances, these agencies may require personnel to secure a license before the Items or Information are exported to another country or shared in the US with foreign nationals from certain countries.

II. POLICY

It is the policy of MSK that all personnel, including employees, visiting scientists, postdoctoral fellows, volunteers, students, and other persons retained by or working at or for MSK conduct their affairs in accordance with US laws and regulations, including compliance with US export control laws and regulations applicable to its operations. The laws and regulations governing exports are detailed and complex. Investigators and other personnel, including those who ship or share Items and Information overseas or with individuals or countries subject to export control regulations or embargoes, are responsible for becoming familiar with and following applicable export control requirements. All MSK employees with managerial or supervisory authority over projects involving Items or Information subject to export controls should view export control compliance as an important part of their day-to-day responsibilities. In an organization like MSK that frequently works in tandem with researchers and collaborators from abroad, it is particularly important to determine the potential requirement for export control authorization early in the process of any international collaboration.

MSK will provide resources to assist investigators and other personnel to comply with US export control laws and regulations. In addition, the Research Outreach and Compliance Office (ROC), is available to answer questions and assist in the process of assessment or application for an export control license. Questions can be sent to: RTMROC@mskcc.org

Export control analysis is very complex and requires a variety of considerations. At the most basic level, investigators must consider a series of questions:

1) Does the Item have military or aerospace applications (appearing on the US Munitions List)?

https://www.pmdtdc.state.gov/regulations_laws/documents/official_itar/ITAR_Part_121.pdf

2) Does the Item being exported appear on the Commerce Control List?

<http://www.bis.doc.gov/index.php/regulations/commerce-control-list-ccl>

3) Is the Item or Information being exported to an embargoed country or sanctioned end-user on one of the State, Commerce, or Treasury Department's lists of entities of concern?

<http://www.bis.doc.gov/index.php/policy-guidance/lists-of-parties-of-concern>

4) Is there any reason to believe the intended recipient plans to transfer or use the export for prohibited purposes?

http://export.gov/ecr/eg_main_023148.asp

If the answer to any of these questions is "yes", then an export control analysis is necessary. The employee who seeks to export an item that may be subject to export controls shall be responsible for alerting ROC to initiate an export control assessment. If a license is required, processing can take a month or more, so early inquiry is recommended. Questions can be sent to: RTMROC@mskcc.org

III. SCOPE

All MSK Investigators and employees and those acting on MSK's behalf are responsible for ensuring that MSK conducts its activities in compliance with the requirements of US export control laws and regulations and the rules and procedures set forth in this Policy. It is particularly important for an organization like MSK that frequently works with international researchers and collaborators to identify early on in the process any activity that may require export control authorizations. This requires full and timely disclosure of all relevant facts in a transaction in a clear, straightforward, and comprehensible manner.

IV. DEFINITIONS

Commerce Control List (CCL): A list maintained in accordance with the Export Administration Regulations by the federal Bureau of Industry and Security including Items that are subject to the export control authority of the Bureau of Industry and Security

(<http://www.access.gpo.gov/bis/ear/pdf/738.pdf>). Items on the Commerce Control List (CCL) include “dual-use” goods and technologies (having both civil and military applications) as well as exclusively civil items. The index to the CCL is located at: http://www.gpo.gov/bis/ear/ear_data.html.

Deemed Exports: Any release of technology or source code subject to the EAR, or disclosing or transferring technical data or performing a defense service under the ITAR, to a foreign national in the United States. Such release is deemed to be an export to the home country or countries of the foreign national. This deemed export rule does not apply to persons lawfully admitted for permanent residence in the United States and does not apply to persons who are protected individuals under the Immigration and Naturalization Act.

Denied Parties: Any party that is denied export privileges by the Department of Commerce. Dealings with denied parties that violate the terms of the denial order are prohibited. For purposes of this policy, denied parties are also defined to include any party or entity listed on the Specially Designated Nationals or Specially Designated Terrorist lists by the Department of Treasury, parties subject to Nonproliferation Sanctions under the Department of State, Arms Export Control Act Debarred entities, individuals and entities on the Foreign Sanctions Evaders List, or are otherwise prohibited from engaging in transactions with US persons.

Dual-use: Items or technologies that have both civilian and military applications. Dual-use materials are covered by the EAR.

EAR: Export Administration Regulations. These regulations are administered by the Department of Commerce, Bureau of Industry and Security.

Effective Control: Retaining physical possession of an item, or securing the item in such an environment as a hotel safe, a bonded warehouse, or a locked or guarded exhibition facility. Retention of effective control over an item is a condition of certain temporary exports.

Empowered Official: A US person employed by MSK with authority to legally sign export licenses and other related requests. This person understands the export regulations and the criminal and civil liabilities and administrative penalties for violating federal export control regulations of military and defense articles.

Export: The shipment, transmission, or carrying (e.g., while traveling abroad) of controlled Items or Information outside the United States, as well as the transfer of technology or “know how” to a foreign national in the United States, which is considered a “deemed” export.

Foreign National: Any natural person who is not a lawful permanent US resident or who is not a protected individual as defined by 8 U.S.C. 1324b(a)(3). It also means any foreign corporation, business association, partnership, trust, society or any other entity or group that is not incorporated or organized to do business in the United States, as well as international

organizations, foreign governments and any agency or subdivision of foreign governments (e.g., diplomatic missions).

Fundamental Research: Basic and applied research in science and engineering, where the resulting information is ordinarily published and shared broadly within the scientific community. Such research can be 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.

Item: Defined by US Export Administration Regulations means commodities, software, and technology.

License: Authority issued by an appropriate federal agency authorizing an export, re-export, or other regulated activity.

Publicly Available: Technology and software that are already published or will be published; arise during, or result from, fundamental research; are educational; or are included in certain patent applications.

OFAC: Office of Foreign Assets Control in the US Department of Treasury is the office responsible for administering and enforcing economic and trade sanctions based on US foreign policy and national security goals. OFAC acts under Presidential national emergency powers, as well as authority granted by legislation.

Re-export: An actual shipment or transmission of export controlled items from one foreign country to another foreign country.

Release: Technology or software is “released” for export through visual inspection, oral exchanges of information in the US or abroad, or the application to situations abroad of personal knowledge or technical information acquired in the US.

Specially Designated Nationals (SDNs): An OFAC compiled list of individuals and companies owned or controlled by, or acting for or on behalf of, targeted countries. It also lists individuals, groups, and entities, such as terrorists and narcotics traffickers designated under programs that are not country-specific. Their assets are blocked and US persons are generally prohibited from dealing with them.

Subject to EAR: Unless excluded in the EAR, all items in the United States, including in a US Foreign Trade Zone or moving intransit through the United States from one foreign country to another; all US origin items wherever located; foreign-made commodities that incorporate controlled US-origin commodities, foreign-made commodities that are ‘bundled’ with controlled US-origin software, foreign-made software that is commingled with controlled US-origin software, and foreign-made technology that is commingled with controlled US-origin technology; certain foreign-made direct products of US origin technology or software; certain

commodities produced by any plant or major component of a plant located outside the United States that is a direct product of US-origin technology or software are subject to the EAR.

Technical Data (EAR): Blueprints, plans, diagrams, models, formulae, tables, engineering designs and specifications, manuals and instructions written or recorded on other media or devices such as disk, tape, read-only memories.

Technical Data (ITAR): Information, other than software, which is required for the design, development, production, manufacture, assembly, operation, repair, testing, maintenance or modification of defense articles. This includes information in the form of blueprints, drawings, photographs, plans, instructions or documentation; Classified information relating to defense articles and defense services on the US Munitions List and 600-series items controlled by the Commerce Control List; Information covered by an invention secrecy order; or Software directly related to defense articles.

Technology: As defined by the Export Administration Regulations means the specific information necessary for the development, production, or use of a product.

Transfer: As defined by the Export Administration Regulations means the shipment, transmission or release to any person of items subject to the Export Administration Regulations, either inside or outside of the United States.

US Munitions List: A list maintained in accordance with the International Traffic in Arms Regulations (ITAR) by the Directorate of Defense Trade Controls (DDTC) of the US Department of State. Items on the US Munitions List (USML) include defense goods, technical data, and defense services.

US Person: A person who is a lawful permanent resident as defined by 8 U.S.C. 1101(a)(20) or who is a protected individual as defined by 8 U.S.C. 1324b(a)(3). It also means any corporation, business association, partnership, society, trust, or any other entity, organization or group that is incorporated to do business in the United States. It also includes any governmental (federal, state or local) entity.

Use Technology: Under the EAR, "use" is defined as the operation, installation, maintenance, repair, overhaul, *and* refurbishing of a material. Use technology is information that is required to "use" the material. This is distinct from ordinary or every-day use, which would not include all six aspects of export controlled use technology.

V. REGULATORY BACKGROUND

Agencies and Regulations Involved

Export controls are based on multiple bodies of federal regulations that are promulgated by several federal agencies in different federal departments. The three main export control regulations are the Export Administration Regulations administered by the Bureau of Industry and Security in the Department of Commerce, the International Traffic in Arms Regulations

from the Directorate of Defense Trade Controls in the Department of State, and various sanctions enforced by the Office of Foreign Assets Control in the Department of Treasury.

Penalties for Violations

In the event of a violation of US export control laws, both MSK and the individuals involved in the violation may be liable. MSK and the individual investigators and personnel involved may be subject to severe administrative and civil sanctions as well as criminal penalties. For example, civil violations of the EAR are punishable by a fine of up to twice the value of the exports involved or \$250,000, whichever is greater. Criminal violations can result in penalties of up to \$1 million per violation and up to 20 years imprisonment. Exports are subject to a strict liability standard, so even negligent exports can trigger fines. Penalties can also include the denial of export privileges, debarment from contracting with the federal government, and a loss of federal funds. Almost all enforcement actions are public.

VI. EXPORT COMPLIANCE POLICY LEADERSHIP

The Senior Vice President, Research and Technology Management is the senior MSK staff member primarily responsible for ensuring that this Policy is properly implemented and followed throughout MSK.

VII. EXPORT CONTROLS AND RESEARCH

Types of Exports

Items and Information are exported when they are shipped, transmitted, or carried out of the US. The transfer of technology or “know how” to a foreign national in the United States may be considered a “deemed” export. Under the deemed export rule, the transfer or release of Information subject to US export controls to a foreign national, whether it occurs in the United States or abroad, is “deemed” to be an export from the United States to the foreign national’s country of residence. At research institutions, this issue may arise in connection with the participation of international researchers or collaborators in projects involving technology controlled relative to the collaborator’s country of residence.

In addition to transferring controlled Items or Information across international boards, “export controls” also generally encompass restrictions in trade or certain forms of technical assistance to: embargoed countries, including countries subject to comprehensive embargoes such as Cuba, Iran, North Korea, Syria, and Sudan, and countries subject to limited sanctions or embargoes such as the Balkans, Cote D’Ivoire (formerly Ivory Coast), Iraq, Liberia, Myanmar (formerly Burma), Zimbabwe, and the Palestinian Territories (Palestinian Authority); to prohibited people or entities; or to recipients who intend to use the Item or Information for prohibited purposes.

Openness in Research Policy

MSK maintains an Openness in Research Policy which states that, with rare exception, the Center will not engage in classified research that cannot be openly disseminated to the research community. See [RTM Policy RTM-1012](#). This policy preserves the Fundamental

Research Exclusion for the majority of research conducted at MSK, taking it outside the scope of the export control regulations.

Fundamental Research Exclusion

The Fundamental Research Exclusion was originally defined by the Reagan Administration in 1985 in National Security Decision Directive 189. This Directive established “national policy for controlling the flow of science, technology, and engineering information” produced through “fundamental research” at colleges, universities, and laboratories.

“Fundamental research’ means basic and applied research in science and engineering, the results of which ordinarily are published and shared broadly within the scientific community, as distinguished from proprietary research and from industrial development, design, production, and product utilization, the results of which ordinarily are restricted for proprietary or national security reasons.”

NSDD-189’s stance that fundamental research should “remain unrestricted” was later codified in the EAR and the ITAR as the Fundamental Research Exclusion (FRE). The FRE broadly excludes from export controls the products of fundamental research. The FRE is maintained by an open research policy as this protects the principles of unrestricted publication and open dissemination upon which NSDD-189 was premised.

VIII. PROHIBITED END-USES AND END-USERS

An investigator’s liability in the transfer of Items, information or technology extends beyond the initial transfer. If an investigator has “knowledge” that the recipient (within the United States or abroad) intends to transfer restricted Items or Information to prohibited end-users or for a use or purpose prohibited by export control regulations, then export control laws, including criminal penalties, are enforceable against the investigator. If an investigator has a question or a concern in this regard, he or she should contact ROC to determine whether a license is required. Investigators should assume that all exports to or transactions involving restricted countries or people or entities from restricted countries (prohibited end-users) require a license. In situations involving prohibited end-users, the investigator must contact ROC. Questions can be sent to: RTMROC@mskcc.org

IX. RESEARCH ACTIVITIES

Contracts with Outside Parties

All research-related contracts with outside parties should have an appropriate Export Control language clause (e.g., vendor/procurement, material transfer agreement*, clinical trial agreement, etc.). If you are unsure about contract language, questions can be sent to: RTMROC@mskcc.org. As appropriate, ROC will consult with the Compliance Department, Environmental Health and Safety Department, General Counsel’s Office and other MSK units (e.g., Office of Technology Development, Office of Research and Project Administration) to assist in evaluating export control concerns.

***eMTA** – those submitting an electronic Material Transfer Agreement ([eMTA](#)) application will be able to answer export control questions within the system. Affirmative answers will trigger an automatic ROC review.

Personnel

Laboratory personnel who are not US persons may engage in research activities normally conducted in the lab and may use lab equipment that is export controlled. The involvement of foreign nationals in a lab's research activities may, however, be restricted in several circumstances. First, if the laboratory enters into a research contract that restricts the involvement of foreign nationals, such contract terms would erode the FRE's application to the research and export control regulations would apply – any export controlled aspects of the research could require licenses from the relevant federal agencies.

Second, if fundamental research conducted in a lab requires export controlled items, those items remain controlled, even though the research itself and its results remain fundamental. If the foreign national will have access to development, production, or use technology related to the controlled item, then a deemed export license may be required for that foreign national to work on the project, or a technology control plan should be implemented such that the foreign national will not have access to the controlled technology while working on the project.

IRS regulations also require an attestation from employers of foreign nationals who are working in the US under H-1B, H-1B1 Chile/Singapore, L-1, and O-1A petitions stating whether or not the foreign national employee's work requires an export license from the Department of Commerce or Department of State.

Visitors

Visitors to MSK laboratories that conduct research with export controlled equipment or technologies should first be screened against Denied Parties lists in order to avoid potential "deemed" exports to unauthorized persons. Because oral communications about or visual display of export controlled technology may constitute a release of that technology, a deemed export license from the appropriate federal agency may be required prior to such a release to a foreign national visitor.

Transfer of Information to Collaborators in the United States

Investigators must assume that they bear responsibility and liability with respect to export control laws even if the transfer of Information is to collaborators and institutions within the United States. As discussed earlier, transfer of technology or Information to a foreign national (either in the United States or abroad) may be considered a "deemed" export to the foreign national's country of residence regardless of where the transfer actually took place.

For the purposes of "deemed" exports, personnel should be aware of all controlled Information within their domain, even if the Information is never intended to be transferred internationally. Export control regulations may require personnel to ensure that local foreign nationals do not have access to the controlled Information or technology.

In most cases, deemed export classification should not be an issue at MSK because of the FRE. In general, Information is protected from export controls if:

The research information will be shared broadly within the scientific community and the general public, is free from publication restrictions, and is not subject to any access or dissemination controls.

OR

The information is disclosed at an accredited university in the U.S, and this disclosure occurs through instruction in catalog courses and/or associated teaching laboratories of academic institutions.

Most Information in an academic research setting is considered to be publically available and, therefore, no license is necessary for access to this information by foreign nationals.

ROC can assist in determining whether export controls apply to Information or technology being used locally and/or whether any controls need to be put in place to restrict work with foreign nationals. Questions can be sent to: RTMROC@mskcc.org

Research Collaborations under Export Control Regulations

Collaborations with investigators both in the United States and around the world may invoke export control regulations. There are four distinct issues with respect to such collaborations: (a) shipment or transmission of Items and certain Information to individuals in prohibited countries, (b) MSK investigators traveling abroad to conduct research in restricted countries, (c) transfer of Information to collaborators within the United States, or (d) transfer of Items or Information to collaborators (domestic or international) who may then, in turn, transfer the Items or Information to others for prohibited purposes.

International Travel and Conducting Research Abroad

Investigators who are conducting research abroad must be aware of potential restrictions involving foreign travel, international shipment of Items, and the transfer of Information to colleagues in foreign countries. Investigators who are traveling abroad must consider what they intend to bring with them and where they are going. Whether an Item is shipped in a package, carried in person or in one's baggage, all Items carried across US borders are considered "exports" and therefore subject to export controls. All Items being shipped or carried must first be assessed to determine if they are classified pursuant to the Export Administrations Regulations, and, if so, that the export is permissible to the specific destination country (based on the Commerce Control List or the US Munitions List). Investigators should assume that a license is required for transfer of items to or activities taking place in embargoed countries (as designated by OFAC). Be aware that material-specific air safety regulations may also apply, including regulations for materials shipped by a commercial transporter, carried or packed in personal baggage, or taken onto an aircraft as a carry-on item.

Laptops are generally permissible to carry without a license based on a “tools of the trade” exception. To qualify for this exception, investigators (or their designees) must ensure that the computer and software are reasonable and necessary for the purpose of use, remain at all times under “effective control” (carried with investigator or locked in secure safe), and be returned to the US as soon as possible and within one year from time of export. Laptops may not be carried at any time or for any purpose to the Sudan. In addition, material stored on the laptops is considered to be exported from the US; so investigators must consider whether any material stored on the laptop requires a license before carrying the laptop internationally.

Generally, sharing Information with foreign colleagues 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. In summary, as long as the Information is published or ordinarily intended for publication, it is considered to be publicly available or in the public domain and therefore allowable. Prior to engaging in research activities or collaborations abroad, investigators should assess whether the research activities, results, or technology required to conduct the research is protected by the fundamental research exemption. If any aspect of the research falls outside of the fundamental research exemption, the investigator should contact ROC, which will help to determine whether a license is required. Questions can be sent to: RTMROC@mskcc.org

For more guidance on traveling abroad with electronic communication devices and/or equipment see Information Security Policy #2015-01, Guidelines for International Travel.

Shipment or Transmission of Materials Abroad

The transfer of certain Items to countries outside the United States may require a license from the United States Commerce Department, State Department, or Department of Treasury prior to any shipment or transmission. The Investigator or individual who ships or transfers the Item or Information to an overseas collaborator is ultimately responsible for ensuring that such shipment complies with all applicable laws. These determinations are complex. Investigators should contact the Research Outreach and Compliance Office, which will help determine whether export controls apply, whether a license is necessary and/or the process for determination and issuance. As appropriate, ROC will consult with the Compliance Department, Environmental Health and Safety Department, General Counsel’s Office and other MSK units (e.g., Office of Technology Development, Office of Research and Project Administration) to assist in evaluating export control concerns.

The transfer of some Items and Information may require approval or a license from the responsible Federal agency before they can be shipped, so it is important to allow sufficient time (60-90 days) to process these requests.

X. GOVERNMENT COMMUNICATIONS: CLASSIFICATION REQUESTS AND EXPORT CONTROL LICENSES

The Senior Vice President, Research and Technology Management is authorized by MSK to sign license applications and other requests for approval, and has the independent authority to

inquire into any aspect of proposed exports or temporary imports into the Center, to verify the legality of transactions, and to refuse to sign any license application. License applications to the Department of State, Department of Commerce, or OFAC will be submitted through the Office of the Senior Vice President of Research and Technology Management in coordination with other MSK departments, as necessary. Individual investigators are not authorized to apply for export licenses. In the event that an export license must be sought from the Department of State, the Senior Vice President, Research and Technology Management, will serve as the Empowered Official as required by the ITAR. Questions can be sent to RTMROC@mskcc.org.

XI. RECORD KEEPING

Under the EAR, all records pertaining to export transactions must be kept for five (5) years from the latest of the following:

- 1) The date of export from the US of the pertinent items;
- 2) The date of any known re-export, transshipment, or diversion of the pertinent items;
- 3) The date of termination of the transaction, whether formally in writing or by other means; or
- 4) If the transaction involves restrictive trade practices or boycotts, the date MSK receives the boycott-related request or requirement.