



INSTITUTIONAL POLICY: R-07

Category: Research
Subject: Export Control
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Updated: **N/A**

R 07-1. Authority

W. Va. Code § 18B-1-6

R 07-2. Purpose

The purpose of this document is to provide a policy governing the Export Compliance Program (“ECP”) for the West Virginia School of Osteopathic Medicine (“WVSOM”) in order to ensure compliance with U.S. export control laws and regulations. These laws generally relate to research products, materials, hardware, software, and technology but may also relate to education and service. WVSOM is committed to export compliance and to ensuring compliance with the variety of federal laws that govern export of these items and information.

R 07-3. Applicability and Scope

All WVSOM employees, students, and affiliates to include those engaged by or visiting the institution are subject to this policy. All WVSOM researchers, employees, and those acting on WVSOM’s behalf are responsible for ensuring that WVSOM activities are conducted in compliance with the requirements of U.S. export control laws and regulations and the rules and procedures set forth in this policy. It is particularly important for WVSOM, which does not frequently work with international researchers and collaborators, to identify early on in the process any activity or information that may require export control authorizations. This will provide sufficient time to ensure all necessary licenses and applications are procured and approved prior to the initiation of the project or delivery of information. This requires full and timely disclosure of all relevant facts in a transaction in a clear, straightforward, and comprehensible manner.

R 07-4. Definitions

4.1 “Commerce Control List” or “CCL” means 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 (<https://www.bis.doc.gov/index.php/regulations/commerce-control-list-ccl>). Items on the CCL include “dual-use” goods and technologies (having both civil and military applications) as well as exclusively commercial items. The index to the CCL is located at: <https://www.bis.doc.gov/index.php/forms-documents/regulations-docs/13-commerce-control-list-index/file>.

- 4.14.2 “Controlled ~~i~~Item or ~~i~~Information” means any tangible good or information/data subject to the Export Administration Regulations. These include items on the Commerce Control List (CCL)—(<https://www.bis.doc.gov/index.php/regulations/commerce-control-list-ccl>) and goods and information on the U.S. Munitions List (<https://www.ecfr.gov/current/title-22/chapter-I/subchapter-M/part-121>).~~<https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=70e390e181ea17f847fa696e47e3140a&mc=true&r=PART&n=pt22.1.121>~~).
- 4.3 “Deemed ~~e~~Export(s)” means releasing or otherwise transferring ~~e~~Export-controlled ~~t~~Technology, information, or source code to a ~~f~~Foreign ~~n~~National located in the U.S., as described in the Export Administration Regulations (EAR), or disclosing or transferring Technical Data or performing a defense service under the International Travel in Arms Regulations (“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.
- 4.4 “Deemed Re-Export” means releasing or otherwise transferring Technology or source code subject to the EAR to a Foreign Person of a country other than the foreign country where the Release or Transfer takes place. For example, a WVSOM researcher sends controlled Technology to a German collaborator under a License or License exception, but they may not release the Technology to a Chinese Foreign National within their lab without a Deemed Re-export License.
- 4.5 “Denied Parties” means 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, and accompanying procedure, 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 (“FSE”) List, or are otherwise prohibited from engaging in transactions with U.S. Persons.
- 4.6 “Effective Control” means 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.
- 4.7 “Empowered Official” means a U.S. Person employed by WVSOM 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.
- 4.8 “Encryption” means the process of encoding a message so that only the sender and the intended recipient can read it.

4.24.9 “Encryption Software” means software whose main task is Encryption and decryption of data, usually in the form of files on hard drives and removable media, or email messages sent over computer networks or the Internet.

4.34.10 “Export” means ~~e~~Controlled ~~i~~Items and ~~i~~Information, (as defined in the EAA), that leave the country and ~~e~~Controlled ~~i~~Items and ~~i~~Information that are shared within the borders of the U.S. with ~~f~~Foreign ~~n~~Nationals subject to the EAA (“~~d~~Deemed ~~e~~Export” defined in the EAA).

4.11 “Export Administration Act” or (“EAA)” means the suite of federal regulations concerning ~~e~~Export control, including but not limited to 31 CFR 500-599 (Foreign Assets Control Regulations), 15 CFR 730-774 (Export Administration Regulations) and 22 CFR 120-130 (International Traffic in Arms Regulations).

4.12 “Export Administration Regulations” or “EAR” means regulations administered by the Department of Commerce, Bureau of Industry and Security.

4.44.13 “Export Control Classification Number” or “ECCN” means a five-character alphanumeric classification used under the EAR to identify items on the CCL.

4.54.14 “Foreign ~~n~~National” or “Foreign ~~p~~Person” means any natural person who is not a lawful permanent U.S. 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 other entity or group that is not incorporated or organized to do business in the United States. In addition, it includes international organizations, foreign governments and any agency or subdivision of foreign governments (e.g. diplomatic missions).

4.15 “Fundamental ~~r~~Research” means research in science, engineering, or mathematics, the results of which ordinarily are published and shared broadly within the scientific community, and for which the researchers have not accepted restrictions for proprietary or national security reasons. (~~EAR~~) Research which meets the standard of ~~f~~Fundamental ~~r~~Research qualifies for the fundamental research exclusion(~~FRE~~), exempting it from ~~e~~Export controls. However, FRE determination should be made in consultation with the Export Compliance Manager (“ECM”).

4.64.16 “Fundamental Research Exclusion” or “FRE” means the exclusion that permits U.S. institutions to allow foreign members of their community (e.g., students, faculty, and visitors) to participate in research projects involving Export-controlled information on campus in the U.S. without the need for a License. The FRE, however, does not generally permit the Transfer of Export-controlled information, materials, or Items abroad. The FRE is null and void if participation in research and/or access to and disclosure of research results is restricted by the sponsor.

4.17 “International ~~e~~Collaboration” means any work with persons who are ~~f~~Foreign ~~n~~Nationals.

4.18 “International Traffic in Arms Regulations” or “ITAR” means regulations administered by the Directorate of Defense Trade Controls (“DDTC”) of the U.S. Department of State.

4.19 “Item” means commodities, software, and Technology as defined by U.S. EAR.

- 4.20 “License” means a written authorization issued by an appropriate federal agency authorizing an Export, Re-export, or other regulated activity and detailing the specific terms and conditions under which such activity is allowed.
- 4.21 “Office of Foreign Assets Control” or “OFAC” means the office the U.S. Department of Treasury responsible for administering and enforcing economic and trade sanctions based on U.S. foreign policy and national security goals. OFAC acts under Presidential national emergency powers, as well as authority granted by legislation.
- 4.22 “Publicly Available” means 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.
- 4.23 “Re-export” means an actual shipment or transmission of Export Controlled Items from one foreign country to another foreign country. Re-exports of EAR Controlled Items typically require a License or other form of government authorization. For example, a research sample might be sent to collaborators in France, but then Re-exported to researchers in Israel, a country with more significant Export restrictions. Analysis of Export licensing requirements must consider the final end user, including any Re-exports.
- 4.24 “Release” means Technology or software released for Export through visual inspection, oral exchanges of information in the U.S. or abroad, or the application to situations abroad of personal knowledge or technical information acquired in the U.S.
- 4.25 “Technical Data” means 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 USML and 600-series items controlled by the CCL information covered by an invention secrecy order; or software directly related to defense articles. The term does not include information concerning general scientific, mathematical, or engineering principles commonly taught in schools, colleges, and universities. It also does not include information in the public domain or basic marketing information on function or purpose or general system descriptions.
- 4.26 “Technology” as defined by the EAR means the specific information necessary for the development, production, or use of a product, but not the product itself.
- 4.27 “Transfer” as defined by the EAR means the shipment, transmission, or release to any person of Items subject to the EAR, either inside or outside of the United States.
- 4.28 “U.S. Munitions List” or “USML” means a list maintained in accordance with the ITAR by the Directorate of Defense Trade Controls (“DDTC”) of the U.S. Department of State. Items on the USML include defense goods, Technical Data, and defense services. The USML is illustrative only and not definitive, meaning that the absence of an Item on the USML does not rule out the possibility of its being a defense article or service.
- 4.29 “U.S. Person” means 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.

4.74.30 “Use Technology” as defined by the EAR means 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.

R 07-5. Export Control Laws and Regulations Overview

- 5.1 Federal ~~e~~Export control laws primarily consist of three separate sets of regulations administered in turn by three independent agencies (“Export Control Regulations”):
 - 5.1.1 Department of Commerce Regulations: [Export Administration Regulations \(EAR\)](#)
Administered by the U.S. Department of Commerce Bureau of Industry and Security. EAR covers "dual use" civilian/military items and ~~t~~Technology and some items that have solely civilian use.
 - 5.1.2 Department of State Regulations: [International Traffic in Arms Regulations \(ITAR\)](#)
Administered by the U.S. Department of State Directorate of Defense Trade Controls. ITAR regulates items and services related to military/defense applications, including spacecraft and satellites.
 - 5.1.3 Department of the Treasury Regulations: [Office of Foreign Assets Control \(OFAC\)](#)
Administered by the U.S. Department of the Treasury, OFAC covers restrictions due to foreign trade embargoes and economic sanctions. It also has regulatory authority over travel and the transfer of funds, services, and items to certain countries, entities, and individuals.
- 5.2 It is important to note that the ~~t~~Transfer or sharing of controlled data, information, software, or ~~i~~Items within the U.S. (even to a foreign student, colleague, or visitor at WVSOM) would still fall under the ~~e~~Export control regulations. Such situations would be classified as a “~~d~~Deemed ~~e~~Export” and defined in the EAR as “a release of ~~e~~Export-controlled ~~t~~Technology, information, or source code to a ~~f~~Foreign ~~n~~National located in the U.S.”. To illustrate, it is obvious to most who are familiar with ~~e~~Export control regulations that controlled bio-sensory equipment would need an ~~e~~Export ~~l~~License before it could be shipped internationally. However, a “~~d~~Deemed ~~e~~Export ~~l~~License” would be needed for a foreign student who is working with the same apparatus in the U.S. It is an often overlooked area, but one that has extremely serious repercussions if not paid attention to.

R 07-6. Export Compliance Program

- 6.1 WVSOM maintains an ECP that is responsible for ensuring that the institution carries out the purpose of this policy. The ECP shall:
 - 6.1.1 Affirm WVSOM’s commitment to ~~e~~Export compliance annually, or more often if necessitated by personnel, management or regulatory changes;

- 6.1.2 Explain the basic purpose of ~~e~~Export controls and its importance in protecting national security and foreign policy interests for the United States;
 - 6.1.3 Monitor sales to ensure no violation, or potential violation, of U.S. ~~e~~Export regulations and laws;
 - 6.1.4 Provide annual training for employees and initial training for entering students on ~~e~~Export controls as a method of ensuring compliance;
 - 6.1.5 Review all international travel and/or collaborations by WVSOM employees and students; and
 - 6.1.6 Maintain records pertaining to ~~e~~Export transactions for at least five years from the latest of the events defined in the EAA.
- 6.2 The ECP is implemented by the Export Control Compliance Committee (“ECCC”) and the Financial Reporting Manager. The ECCC is described in the ECP manual and chaired by the ECM. The ~~f~~Financial Reporting Manager monitors sales as described in Section 6.1.3 above. The ECCC consists of the Vice President ~~for of~~ Academic Affairs and Dean (“VPAAD”); the Associate Dean ~~for of~~ Research and Sponsored Programs, who serves as the ~~Export Compliance Manager~~ (ECM); the ~~Chief Technology Officer~~ Executive Director of Information Technology; the Institutional Compliance Officer; the Vice President ~~for of~~ Human Resources; and the Associate Dean ~~for of~~ ~~Predoctoral~~ Clinical Education. The Research Integrity and Compliance Administrator will serve as an ex officio member of the ECCC.

R 07-7. Administration of the ECP

- 7.1 The Office of Research and Sponsored Programs (“ORSP”) shall oversee the day to day administration of the ECP and ensure that communication is maintained among employees, students, the ECCC, and the Financial Reporting Manager.
- 7.2 The ORSP shall be equipped with the necessary resources to perform the administrative functions of the ECP, including:
 - 7.2.1 Maintenance of records;
 - 7.2.2 Scheduling meetings of the ECCC as needed;
 - 7.2.3 Initiating review of the ECP every three (3) years or as new or modified regulations are promulgated;
 - 7.2.4 Facilitating sponsored program applications involving ~~i~~International ~~e~~Collaborations; and
 - 7.2.5 Accessing and distributing current regulatory and guidance information to relevant parties as needed to maintain an ~~e~~Export control process of excellence.
- 7.3 The Associate Dean ~~for of~~ Research and Sponsored Programs will serve as the ECM and point of contact for employees, students, visitors, and all others with questions about the ECP.

R 07-8. Institutional Commitment

- 8.1 WVSOM will affirm its commitment to ~~e~~Export compliance annually or more often if necessitated by personnel, management, or regulatory changes.
- 8.2 The annual Management Commitment Statement will include the following:
 - 8.2.1 A statement affirming the ~~Institution's~~WVSOM's commitment to ~~e~~Export compliance and commitment of appropriate resources to compliance;
 - 8.2.2 An explanation of the basic purpose of ~~e~~Export controls and its importance in protecting national security and foreign policy interests for the United States;
 - 8.2.3 A statement that no sale under any circumstances will be made that violates or potentially violates the U.S. ~~e~~Export regulations and laws;
 - 8.2.4 A description of the importance of employees being familiar and compliant with ~~e~~Export controls, so that employees understand possible non-compliance scenarios and specific risks as they relate to ~~the Institution's~~WVSOM's products, ~~t~~Technology, destinations and activities;
 - 8.2.5 A description of the risk of unauthorized ~~t~~Transfers for even low-level ~~t~~Technology which could potentially jeopardize national security or further the development of weapons of mass destruction;
 - 8.2.6 A description of the possible penalties that ~~the Institution~~WVSOM and individual could face for non-compliance, including loss of ~~e~~Export privileges, disciplinary action, damage to the individual and ~~Institution's~~WVSOM's reputation, criminal penalties and administrative/civil penalties and fines; and
 - 8.2.7 The name and contact information of the Export Compliance Manager in the case of questions.

R 07-9. Review and Approval of International Travel and/or Research

- 9.1 All international travel (research and non-research related) will be reviewed and authorized by the ECM to ensure compliance with the federal regulations. International travel that has been approved by the ECM may be subject to modification as more information is provided or if the EAA changes.
- 9.2 All sponsored projects (research and non-research) involving ~~t~~International ~~e~~Collaborations (both outside and within U.S. borders) will be reviewed and approved by the ECM to ensure compliance with the federal regulations. Sponsored projects that have been approved by the ECM may be subject to modification as more information is provided or if the EAA changes.
- 9.3 The ECM will independently make routine decisions about travel and sponsored projects as they relate to ~~e~~Export control compliance. More complex or possibly high-risk matters will be directed onto the ECCC for review and authorization.
- 9.4 The ECCC will be informed regarding all reviews and decisions made by the ECM on a bi-monthly basis through a summary report.

R 07-10. Record Keeping

Export Administration Regulations require ~~e~~Export transactions to be kept for a minimum of five (5) years from the latest of:

- 10.1 The date of the ~~e~~Export from the U.S. of the ~~i~~Items in question;
- 10.2 The date of any known ~~r~~Re-export, transshipment, or diversion of the ~~i~~Items in question;
- 10.3 The date of termination of the transaction, whether formally in writing or by other means; or
- 10.4 If the transaction involves restrictive trade practices or boycotts, the date WVSOM receives the boycott-related request or requirement.

R 07-11. Procedures

WVSOM's ORSP shall maintain an ECP Standard Operating Procedures manual (~~ECP SOP~~) to implement this policy. Such operating procedures must be approved by the ECCC following the requirements set forth in WVSOM's Procedure for the Adoption, Amendment, or Repeal of Institutional Operating Procedures.

R 07-12. Implementation of Policy

This policy will be implemented using applicable WVSOM policies and procedures, including the ECP Standard Operating Procedures.

R 07-13. References

~~13.1~~ Commerce Control List – <https://www.bis.doc.gov/index.php/regulations/commerce-control-list-ccl>

~~13.2~~ U.S. Munitions List 22 CFR Part 121

~~13.3~~ Export Administration Regulations 15 CFR Parts 730-774

~~13.4~~ International Traffic in Arms Regulations 22 CFR Part 120-130

~~13.5~~ Office of Foreign Assets Control, Department of Treasury Regulations 31 CFR Parts 500-599 - <https://ofac.treasury.gov/about-ofac>

~~13.6~~ Export Control Reform Act 50 U.S. Code Chapter 58 §4801 and EAR, ITAR, and OFAC Regulations

~~13.7~~ WVSOM ECP Standard Operating Procedures