



## EXPORT CONTROL STANDARD OPERATING PROCEDURES MANUAL

### 1. PURPOSE

- 1.1 WVSOM is committed to educating students from diverse backgrounds, supporting and developing graduate medical education, advancing scientific knowledge and promoting patient-centered, evidence-based medicine. Though WVSOM is dedicated to serve, first and foremost, the state of West Virginia and its residents, and emphasizes primary care in rural areas, achieving these aims sometimes involves global engagement that is crucial to our students' education and our faculty's research and service endeavors. With this global engagement comes important legal obligations. The Export Administration Act ("EAA") and corresponding regulations, are designed to protect U.S. national security interests. WVSOM is committed to compliance with all applicable Export controls in the EAA and the Export Administration Regulations ("EAR"). This commitment extends to promoting strict compliance on an on-going basis with their terms and conditions.
- 1.2 This manual is designed to assist WVSOM faculty, staff, and students in complying with U.S. Export controls. Questions regarding the material contained in this Export Control Standard Operating Procedures Manual, should be directed to the WVSOM Office of Research and Sponsored Programs ("ORSP") whose staff is available to answer Export control questions (e.g., assessment or application for an Export control License). Questions can be sent to: [export@osteo.wvsom.edu](mailto:export@osteo.wvsom.edu).
- 1.3 Critical to WVSOM's mission is education of students with diverse backgrounds, advancing scientific knowledge, and providing rural, primary care learning opportunities. To do so, WVSOM collaborates with international partners on educational opportunities, research, and services, and hosts foreign visitors through a variety of activities. These are all important functions and WVSOM intends to continue to welcome all such collaborations in a manner consistent with the principles of its mission and Osteopathic Medicine while also ensuring compliance with U.S. laws and regulations governing the Export of certain Items and Information. Under WVSOM Institutional Policy R-07: Export Control, all employees, students and affiliates, including those engaged by or visiting the institution (hereinafter referred to as "WVSOM Personnel"), must comply with the United States Export Control Regulations. Exports shall not be made contrary to U.S. Export Control Regulations by any individual as described above.

### 2. DEFINITIONS

For purposes of this Export Control Standard Operating Procedures Manual, the capitalized terms used herein have the meanings assigned to them in Institutional Policy R-07: Export Control.

### 3. SCOPE

- 3.1 All WVSOM Personnel are responsible for ensuring that WVSOM conducts its activities in compliance with the requirements of U.S. Export Control laws and Regulations and the rules and procedures set forth in the WVSOM Export Control Policy. It is particularly important for WVSOM to identify early in the process any activity that may require Export control authorizations. This will provide time to ensure all necessary Licenses and applications are procured before initiation of the project. This requires full and timely disclosure of all relevant facts in a transaction in a clear, straightforward, and comprehensive manner.
- 3.2 All international travel or domestic collaborations with Foreign Nationals (research and non-research related) will be reviewed and authorized by the WVSOM Export Compliance Manager ("ECM") to ensure compliance with federal regulations. The Associate Dean of Research and Sponsored Programs ("ADRSP") serves as the ECM and point of contact for WVSOM Personnel and all others with questions about the Export Control Program ("ECP"). The ECM will independently make routine decisions about travel and sponsored projects as they relate to Export control compliance. More

complex or possible high-risk matters will be directed onto the Export Control Compliance Committee (“ECCC”) for review and authorization.

#### 4. POLICY

- 4.1 It is the policy of WVSOM (<https://www.wvsom.edu/policies/r-07>) that all WVSOM Personnel conduct their affairs in accordance with U. S. laws and regulations, including compliance with U.S. Export Control laws and Regulations applicable to its operations. The laws and regulations governing Exports are detailed and complex. WVSOM 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 WVSOM 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 responsibilities.
- 4.2 It is important to determine the potential requirement for Export control authorization early in the process of any International Collaboration. Additionally, the EAA does not only apply to research; it may apply to travel for work or educational purposes as well. WVSOM will provide resources to assist Research Personnel in complying with U.S. Export Control laws and Regulations. In addition, ORSP is available to answer questions and assist in the process of assessment or application for an Export control License. Questions can be sent to: [export@osteo.wvsom.edu](mailto:export@osteo.wvsom.edu).
- 4.3 Export control analysis is very complex and requires a variety of considerations. It is also important to note that “Export” does not always mean sharing or dissemination of Items or Information outside the U.S. It could mean sharing of Information or Items to individuals within the U.S. who are designated as a Foreign National (see “Deemed Export”, defined below). At the most basic level, WVSOM Personnel must consider the following questions, regardless of the type of activity they are undertaking (e.g. research, education, service, etc.):
  - 4.3.1 Does the Item or Information have military or aerospace applications (appearing on the U.S. Munitions List)? (e.g., certain microorganisms that could be weaponized)
  - 4.3.2 Does the Item or Information being Exported appear on the Commerce Control List? (e.g., certain types of sensors, lasers, microorganisms, or toxins)
  - 4.3.3 Does the project involve research containing source code for encrypted software (other than Publicly Available software distributed at no charge)?
  - 4.3.4 Does the project restrict participation of WVSOM Personnel based on country of origin or citizenship?
  - 4.3.5 Are Items or Information being transported or sent to an embargoed country or sanctioned end-user on one of the State, Commerce, or Treasury Department’s lists of entities of concern?
  - 4.3.6 Is there any reason to believe the intended recipient plans to Transfer (i.e., Re-Export) or use the Export for prohibited purposes? (e.g., an individual on the Denied Persons List)
- 4.4 If the answer to any of these questions is “yes” or “unknown”, an Export control analysis is necessary. Any WVSOM Personnel who seek to Export an Item that may be subject to Export controls shall be responsible for alerting ORSP 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: [export@osteo.wvsom.edu](mailto:export@osteo.wvsom.edu).

## 5. BACKGROUND

- 5.1 Agencies and Regulations Involved. Export controls are promulgated through several federal regulations that are administered by multiple agencies in different federal departments. The primary Export Control Regulations are the EAR administered by the Bureau of Industry and Security in the Department of Commerce (15 CFR 730-774), the ITAR from the Directorate of Defense Trade Controls in the Department of State (22 CFR 120-130), and various sanctions enforced by the Office of Foreign Assets Control in the Department of Treasury (31 CFR 500-599).
- 5.2 Penalties for Violations. The penalties for violation of U.S. Export Control Policy are severe and may involve both criminal (e.g. incarceration) and civil (e.g. heavy fines) sanctions. Both WVSOM and the individuals involved may be accountable if there is a violation of U.S. Export Control Regulations. The most common violation of the ITAR may be punishable by a fine of over \$1,000,000 (one million dollars). Criminal violations can result in up to 20 years of 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. The U.S. government has made enforcing Export control a priority, as has WVSOM. WVSOM may impose severe administrative penalties on anyone who is found to have violated Institutional Policy R-07: Export Control Policy, even if unintentionally. It is important to understand that most Export Control Regulations apply to research activities, but many also apply to educational, service, and other activities. Thus, this manual describes how to ensure compliance with Export control, regardless of the type of activity being undertaken.
- 5.3 Openness in Research Approach. WVSOM maintains an Openness in Research approach, the goal of which, with rare exception, is to ensure that WVSOM will not engage in classified research that cannot be openly disseminated to the research community. This approach preserves the Fundamental Research Exclusion for the majority of research conducted at WVSOM, taking it outside the scope of the Export Control Regulations.
- 5.4 Fundamental Research Exclusion
  - 5.4.1 The FRE was originally defined by the Reagan Administration in 1985 in National Security Decision Directive 189 (NSDD-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.
  - 5.4.2 “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.”
  - 5.4.3 NSDD-189’s stance that Fundamental Research should “remain unrestricted” was later codified in the EAR and the ITAR as the FRE. The FRE broadly excludes from Export controls the products of Fundamental Research (e.g., publications, presentations) but not the data or documents generated by such 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.
  - 5.4.4 The FRE can be lost if the research sponsor (whether that be government, corporation, or other third party) restricts publication or Release of Information, the sponsor has approval rights on publication, access to the research is restricted (e.g., through a non-disclosure agreement), or the investigator accepts a deal or other agreement with the sponsor not approved by WVSOM.

5.5 Educational and Publicly Available Exclusions. Information that is commonly taught for instruction in courses and associated with general scientific, mathematical, or engineering principles is generally excluded from Export Control Regulations. Additionally, Information that is generally accessible to the public (e.g. through libraries, public seminars, public patents, etc.) is also generally exempt from Export control oversight. However, this exclusion does not necessarily apply to information on internet sites.

## 5.6 Guidance on Types of Exports

5.6.1 The Department of Commerce Bureau of Industry and Security (“BIS”) encourages exporters/investigators to use the detailed descriptions in the CCL to identify the potential ECCN of Items to be Exported. However, in the event of an incorrect classification, the exporter/investigator is liable for any resulting violations of the EAR and may be subject to penalties. Considering where responsibility falls in Export control matters, it is always advisable that the investigator request the assistance of ORSP in making determinations regarding whether EAR applies in any relevant situation.

5.6.2 In addition to transferring Controlled Items or Information across international boundaries, “Export controls” also generally encompass restrictions in trade or certain forms of technical assistance to: embargoed countries, including countries subject to comprehensive embargoes and countries subject to limited sanctions or embargoes; to prohibited people or entities; or to recipients who intend to use the Item or Information for prohibited purposes. This list may not be accurate and changes daily. The most up-to-date list of OFAC embargo/sanction countries may be accessed at <https://www.ofac.treasury.gov/sanctions-programs-and-country-information>.

## 6. EXPORT CONTROL COMPLIANCE COMMITTEE

The WVSOM staff member primarily responsible for ensuring that the WVSOM Export Control Policy is properly implemented and followed throughout WVSOM is the ADRSP. The Empowered Official to whom the ADRSP answers regarding the ECP is the Vice President of Academic Affairs and Dean. The ADRSP chairs WVSOM’s ECCC. This committee is composed of the Chair, the VPAAD, the Executive Director of Information Technology, the Institutional Compliance Officer, the Vice President of Human Resources, and the Associate Dean of Clinical Education. The Research Integrity and Compliance Administrator will serve as an ex officio member of the ECCC. Ad-hoc members may be asked to review or contribute as appropriate.

## 7. EXPORT CONTROLS AND NON-RESEARCH

7.1 Application of Export controls to non-research activity. The majority of WVSOM global engagement activity is educational and/or service related. The extent to which Export controls apply to such activity varies depending on the location of the activity and the non-U.S. Persons involved. If traveling to, or collaborating with (even on non-research programs), citizens of OFAC embargoed countries, Export Control Regulations likely apply. Additionally, if Exporting any Controlled Items (e.g. certain types of Technology or sensors), even in a non-research capacity, Export Control Regulations likely apply. (For example, specific kinds of infrared camera Technology are on the list of Commerce Control List of Controlled Items. Thus, if travelling internationally through a program at WVSOM and taking a camera with infrared Technology (or design Information about such cameras), check that the Item is NOT on the CCL.) If in doubt, contact WVSOM’s ORSP.

### 7.2 International Travel

7.2.1 Activities involving international travel sanctioned by WVSOM will be reviewed by the Export Control Manager (whether research related or not). WVSOM Personnel are required to provide a brief description of the international trip or collaboration, including destination,

duration, specific travel route to and from, activities being undertaken, and any WVSOM property being transported. To ensure Export control compliance on WVSOM's end, it is WVSOM's policy that no WVSOM property or Information shall be brought or carried by any WVSOM Personnel on a personal trip (e.g., any school laptop may not be brought on a personal, international trip), unless a TMP exclusion form is completed and provided to the ORSP. The ORSP will review and if appropriate, approve, after consultation with the Executive Director of Information Technology. The WVSOM Information Technology department may provide a loaner laptop appropriate for international travel.

- 7.2.2 It is important for WVSOM Personnel to keep in mind that foreign travel can generate unforeseen situations that would normally not cause concern. For example, if one travels to a foreign country, logs into his/her cloud account, and retrieves Controlled Information to review, the traveler has exported the data to the country one is visiting because the Information crossed that country's communication lines. An Export License would be required. The cloud provider would likely not have responsibility or legal liability in such cases.

## **8. EXPORT CONTROLS AND RESEARCH**

- 8.1 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. 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, WVSOM Personnel should assess whether the research activities, results, or technologies required to conduct the research are protected by the FRE. If any aspect of the research activity falls outside of the Fundamental Research Exemption or if there is any doubt, the investigator should contact ORSP, which will help to determine whether a License is required. Questions can be sent to: [export@osteo.wvsom.edu](mailto:export@osteo.wvsom.edu).
- 8.2 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 unsure about contract language, questions can be sent to: [export@osteo.wvsom.edu](mailto:export@osteo.wvsom.edu). As appropriate, ORSP will consult with the General Counsel's Office, the Contracts office, and other WVSOM units (e.g., Office of Information Technology) to assist in evaluating Export control concerns.
- 8.3 Personnel
- 8.3.1 Laboratory personnel who are not U.S. 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.
- 8.3.2 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, 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.
- 8.3.3 IRS regulations also require an attestation from employers of Foreign Nationals who are working in the U.S. 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.

- 8.4 Visitors. Visitors to WVSOM research 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.
- 8.5 Transfer of Information to Collaborators in the United States
- 8.5.1 WVSOM Personnel must assume that they bear responsibility and liability with respect to Export control laws even if the Transfer of Controlled 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.
- 8.5.2 For the purposes of “Deemed” Exports, WVSOM 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 WVSOM Personnel to ensure that local Foreign Nationals do not have access to the Controlled Information or Technology.
- 8.5.3 In most cases, Deemed Export classification should not be an issue at WVSOM because of the FRE. In general, Controlled Information is protected from Export controls if:
- a. 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
  - b. 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.
- 8.5.4 Most Information in an academic research setting is considered to be Publicly Available and, therefore, no License is necessary for access to this Information by Foreign Nationals.
- 8.5.5 ORSP can assist in determining whether Export controls apply to Controlled 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: [export@osteowvsom.edu](mailto:export@osteowvsom.edu).
- 8.6 Research Collaborations under Export Control Regulations
- 8.6.1 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) WVSOM 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. Principal Investigators are required to adhere to Export Control Regulations when interacting with collaborators or colleagues.
- 8.6.2 Activities involving research collaborations involving Foreign Nationals (U.S. or non-U.S. based) by WVSOM will be initially reviewed by the ECM who reports findings to the Export Control Committee. WVSOM Personnel are required to provide a brief description of the International Collaboration, including with whom, where the collaborator(s) is from, duration, activities being undertaken, and any WVSOM Controlled Items or Information being shared with the collaborators.

## 8.7 International Travel and Conducting Research Abroad

- 8.7.1 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 U.S. 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 EAR, and, if so, that the Export is permissible to the specific destination country (based on the CCL or the USML).
- 8.7.2 Investigators should assume that a License is required for Transfer of Controlled Items to or activities taking place in OFAC embargoed countries. 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.
- 8.7.3 Laptops are generally permissible to carry without an Export License. However, the 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 the investigator or locked in a secure place such as an hotel safe or guarded exhibition facility), and be returned to the U.S. as soon as possible and within one year from time of Export. In addition, material stored on the laptops is considered to be exported from the U.S.; so investigators must consider whether any material stored on the laptop requires an Export License before carrying the laptop internationally. It is also important to note that certain kinds of Encryption Software are subject to Export Control Regulations, and many laptops and other devices being used in everyday work and leisure contain Encryption Technology which may be restricted or prohibited by either the U.S. or the country to which it is being imported or visited. The foresight and responsibility for dealing with all such scenarios falls to WVSOM personnel, so one should always contact ORSP for consultation and advice to determine if Export Control Regulations apply.

## 8.8 Shipment or Transmission of Materials Abroad

- 8.8.1 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 ORSP, which will help determine whether Export controls apply, whether a License is necessary and/or the process for determination and issuance. As appropriate, ORSP will consult with the General Counsel's Office and other WVSOM units (e.g., Office of Information Technology) to assist in evaluating Export control concerns.
- 8.8.2 The Transfer of some Items and Information may require approval or a License from the responsible Federal agency before they can be shipped. It is important to allow sufficient time (60-90 days) to process these requests.

## 9. PROHIBITED END-USES AND END-USERS

- 9.1 A WVSOM Personnel member's liability in the Transfer of Controlled 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 WVSOM Personnel member. If a WVSOM

Personnel member has a question or a concern in this regard, he or she should contact ORSP to determine whether an Export License is required.

- 9.2 WVSOM Personnel should assume that all exports to or transactions involving restricted countries or people or entities from restricted countries (prohibited end-users) require an Export License. The federal government considers receiving an Export License as a privilege and with it comes great responsibility. The receiving of the License is not to be interpreted as fulfillment of oversight obligation. As mentioned earlier in this document, the exporter/investigator is liable for any resulting violations of the EAR and may be subject to penalties.
- 9.3 In situations involving prohibited end-users, the investigator must contact ORSP. Questions can be sent to: [export@osteo.wvsom.edu](mailto:export@osteo.wvsom.edu).

## **10. GOVERNMENT COMMUNICATIONS: CLASSIFICATION REQUESTS AND EXPORT CONTROL LICENSES**

At WVSOM, the VPAAD is authorized 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 to WVSOM, 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 ORSP in coordination with other WVSOM 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 VPAAD, will serve as the Empowered Official as required by the ITAR. Questions can be sent to [export@osteo.wvsom.edu](mailto:export@osteo.wvsom.edu).

## **11. RECORD KEEPING**

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

- 11.1 The date of Export from the U.S. of the pertinent Items;
- 11.2 The date of any known Re-Export, transshipment, or diversion of the pertinent Items;
- 11.3 The date of termination of the transaction, whether formally in writing or by other means; or
- 11.4 If the transaction involves restrictive trade practices or boycotts, the date WVSOM receives the boycott-related request or requirement.

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**APPROVED BY:**

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