

VANDERBILT UNIVERSITY
MEDICAL CENTER

Policy: Compliance with U.S. Export Control Law and Regulation

Category	Compliance
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Effective Date	May 2023
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Applicable to VUMC Areas (and associated workforce members):

☒ Compliance ☒ Finance ☒ Hospitals and Clinics ☒ Human Resources
☒ Information Technology ☒ Research

Approval Committee(s)

☐ Compliance and Corporate Integrity Committee ☐ VUMC Board of Directors

Content Expert(s)

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I. Purpose:

It is the policy of Vanderbilt University Medical Center (VUMC) to comply with all applicable United States export control laws and regulations, including, but not limited to, the **Export Administration Regulations** (“EAR”) (15 C.F.R. §730-744), the **International Traffic in Arms Regulations** (“ITAR”) (22 C.F.R. § 120-130), and the economic sanctions programs administered by the U.S. Department of the Treasury’s **Office of Foreign Assets Control** (“OFAC”) (as set forth in 31 C.F.R. §500-598 and certain executive orders). Export control laws and regulations restrict the transfer of certain items and information, such as software, equipment, technical data, and other technology and information to anyone outside the U.S., or to **foreign nationals**, wherever located, without a license from the federal government or applicable license exception. While many research activities at VUMC qualify for certain exclusions from U.S. export control laws and regulations, such as the **fundamental research exclusion**, other activities may be restricted.

II. Policy:

A fundamental principle of VUMC is that the teaching and research environment should be open so that ideas can be published and exchanged freely among faculty, staff, students, and trainees. Publications, presentations at professional meetings and student dissertations and theses are an integral part of the VUMC research mission and should remain unencumbered by external restrictions. However, VUMC recognizes that instances may arise in which some VUMC research or activities will involve **technology, technical**

data, information, materials or equipment that are subject to **restrictions** on **access, participation, publication** and/or **dissemination** are propriety in nature, or are subject to specific national security controls and are therefore subject to U.S. export control regulations.

It is the responsibility of all VUMC employees to understand any export control requirements related to their work and to ensure that no **exports** or transfers are made contrary to those requirements. This includes abiding by both the export rules and regulations set forth by the United States Government as well as any policies and procedures established by VUMC with respect to those rules and regulations. It also includes understanding the export implications of research and other activities undertaken at VUMC and obtaining the proper license or identifying and documenting the applicable license exceptions prior to the export or transfer of any export-controlled item (including technology), whether abroad or within the U.S.

Particularly, VUMC employees must ensure that:

- No item of equipment or biological or chemical material is sent outside the U. S. or to any foreign national (wherever located) without first determining if an export license is required; and, if required, obtaining a license.
- All domestic and international shipments are in conformance with applicable regulations governing the licensing, packaging, and shipment of the material; and
- All transfers of export-controlled technology or technical data, whether to an individual in a foreign country or to a foreign national in the U.S. ("**deemed export**"), are in compliance with applicable export control regulations and VUMC policy.

Failure of any VUMC employee to comply with this Policy and/or the requirements of any applicable export control law and regulations may result in the imposition of sanctions by appropriate VUMC officials up to and including termination of employment, as well as the possibility of prosecution by the federal government and the imposition of federal, civil, criminal and/or administrative penalties or sanctions.

III. **Definitions:**

- A. Access Restrictions: Controls placed on access to export-controlled articles or technology based on nationality.
- B. Deemed Export: A release of technology or source code that is subject to the Export Administration Regulations (EAR) to a foreign national (wherever located). Such release is "deemed" to be an export to the home country or countries of the foreign national even when that foreign national is located within the United States.
- C. Dissemination Restrictions: Controls placed on confidential material, knowledge, information, or foreign nationals that either restricts access or prohibits their engagement in an activity.

- D. Export: An actual shipment of articles or related technology/technical data out of the United States or providing export-controlled technical data or technology to restricted parties anywhere, including within the United States.
See: Deemed Export
- E. Export Administration Regulations: (“EAR”) The EAR regulates the export of commercial and “dual-use” items. (15 CFR § 730-774)
- F. Fundamental Research: 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.
- G. Fundamental Research Exclusion: Research that qualifies as Fundamental Research is NOT subject to export controls as provided for under the federal regulations. (15 CFR §734.8)
Note: Research will not be considered 'fundamental' if:
1. The institution or its researchers accept restrictions on publication of scientific and/or technical information resulting from the project or activity; or,
 2. The research is funded by the U.S. Government and specific access and dissemination controls protecting information resulting from the research are applicable.
- H. Foreign National: Any person who is not a citizen or a lawful permanent resident of the United States.
Notes:
1. This definition includes *representatives* of foreign corporations, associations, and governments.
 2. The term "foreign national" or "foreign person" (as defined by 8 U.S.C. 1324b(a)(3)) does **not** include:
 - a. U.S. citizens;
 - b. foreign-born persons who have become naturalized U.S. citizens;
 - c. foreign-born persons who have been lawfully:
 - i. admitted for permanent residence in the U.S. (i.e. holders of "Green Cards"); or
 - ii. designated as refugees; or
 - iii. granted political asylum in the U.S.
- I. International Traffic in Arms Regulations: (“ITAR”) ITAR regulates items and information inherently military in design, purpose, or use. (22 CFR § 120-130)
- J. Office of Foreign Assets Control Regulations: (“OFAC”) OFAC administers and enforces economic and trade sanctions based on US foreign policy and national security goals against targeted foreign countries and regimes, terrorists, international narcotics traffickers, those engaged in activities related to the

proliferation of weapons of mass destruction, and other threats to the national security, foreign policy or economy of the United States. (31 CFR § 501-598)

- K. Participation Restrictions: Controls placed on foreign nationals that prohibit their engagement in an activity.
- L. Publication Restrictions: Controls placed on the free and open dissemination of any information, by any means, in any format, and by any party.
- M. Technology: Refers to specific information necessary for the development, production, or use of a controlled product.
1. Note: This definition does not include information concerning general scientific, mathematical or engineering principals commonly taught in schools, colleges and universities, or information in the public domain.
 2. EAR-specific: 15 CFR §772.
- N. Technical Data: Refers to information required for the design, development, production, manufacture, assembly, operation, repair, testing, maintenance, or modification of a defense article (military specific).
- This includes information in the form of blueprints, drawings, plans, instructions, diagrams, photographs, formulae, tables, engineering designs and specifications, and manuals and instructions written, recorded, or contained on media or devices such as disk, tape, or storage device. Software also comes under the general definition of "technical data."
1. Note: This definition does not include information concerning general scientific, mathematical or engineering principals commonly taught in schools, colleges and universities, or information in the public domain.
 2. ITAR-specific: 22 CFR §120.10.

IV. **Specific Education:**

Specific educational requirements will be described in a Procedure for VUMC Export Compliance training.

V. **Documentation:**

While VUMC Export Compliance will keep records for all transactions, all VUMC employees engaging in export activities are expected to keep all files, emails, and documentation in coordination with their efforts via the document retention guidelines below.

- Retain all files and VUMC Export Compliance interactions in your records for 5 years from the last date of activity on the project, study, travel, shipment, and/or use of controlled material/technology.

VI. **Endorsement:**

Compliance and Corporate Integrity Committee

May 2023

VII. Approval:

Wright Pinson
CEO of Vanderbilt Health System
Deputy CEO of Vanderbilt University Medical Center
Chair, Compliance and Corporate Integrity Committee

May 16, 2023

VIII. References:

- Export Administration Regulations (“EAR”) (15 C.F.R. §730-744)
- International Traffic in Arms Regulations (“ITAR”) (22 C.F.R. § 120-130)
- Economic sanctions programs administered by the U.S. Department of the Treasury’s Office of Foreign Assets Control (“OFAC”) (as set forth in 31 C.F.R. § 500-598)
- Immigration and Nationality Provisions (8 U.S.C. 1324b(a)(3))