Export Management and Compliance Program Guide

UAMS
UNIVERSITY OF ARKANSAS
FOR MEDICAL SCIENCES

Contents

Introduction

UAMS is committed to compliance with all applicable export control laws and regulations that pertain to the conduct and dissemination of our research and to the export of tangible items such as equipment, components, or materials. While our primary mission is patient care, education, research and dissemination of knowledge, the responsibility remains to balance the services of this mission with safeguarding national assets through adherence of the export regulations, rules and laws of our country.

The purpose of this manual is to provide the UAMS community the essential aspects of the laws and regulations concerning exports, confirm our policy for compliance, and explain how UAMS will provide our researchers with the assistance they may need to ensure compliance with these complicated laws.

UAMS Policy

The UAMS Export Control Policy is located here.

Export Controls and University Research

Export controls are federal **laws and regulations** that **regulate and restrict** the **release of critical materials and services** to foreign nationals and foreign countries for reasons of national security, foreign policy, anti-terrorism or nonproliferation. When faculty, staff, and students look to collaborate internationally or with foreign persons within the US or abroad, individuals are dealing with the Export Control Regulations of the United States, as defined below. Export control regulations **apply to all activities** – not just sponsored research.

The three main export regulations applicable to UAMS are the International Traffic in Arms Regulations (ITAR), the Export Administration Regulations (EAR), and the Office of Foreign Assets Control (OFAC). However, other federal agencies also regulate the export, re-export or re-transfer of certain items and technologies: the Nuclear Regulatory Commission (nuclear equipment and materials), the Department of Energy (nuclear technology, high-energy lasers, etc.), the Food and Drug Administration (drugs and medical devices) and the Drug Enforcement Agency (drugs and certain chemicals). (All aforementioned regulations are collectively referred to herein as the "Export Control Regulations").

How does the US Government Control Exports

The US Government controls exports primarily by examining four factors and the related mechanisms. They are:

> 1. The destination – Treasury Department's *Office of Foreign Assets Control* (OFAC)

2. The good or service – The Department of Commerce through its *Export Administration Regulations* (EAR), and the State Department through its *International Traffic in Arms Regulations* (ITAR).
3. The end user – OFAC, EAR
4. The end use – Part 744 of the EAR

It is important to remember goods or services can have dual use. Dual use items are those that have military and civil applications. It is important to screen goods and services against Export Control Regulations because of the potential of dual use.

Depending on the applicability of OFAC, EAR, and ITAR regulations, an export may not be permitted or a license may be required.

What is an Export

Export controls cover all fields of science and engineering. In the Export Control Regulations, there are several meanings to the term "export" which include the following:
- Actual shipment of any covered goods or items;
- The electronic or digital transmission of any covered goods, items, or related goods or items;
- Any release or disclosure, including verbal disclosures or visual inspections, or any technology, software or technical data to any foreign national, even to a foreign national within the United States; ("deemed export") or
- Actual use or application of covered technology on behalf of or for the benefit of any foreign entity or person anywhere.

Thus, any item that is sent from the United States to a foreign destination is an export. "Items" include commodities, software or technology, such as medical equipment, laboratory equipment, biologicals, investigational drugs, novel compounds, software packages, and technical information.

How an item is transported outside of the United States does not matter in determining export license requirements. For example, an item can be sent by regular mail or hand-carried on an airplane. A set of schematics can be sent via facsimile to a foreign destination, software can be uploaded to or downloaded from an Internet site, or technology can be transmitted via e-mail or during a telephone conversation. Regardless of the method used for the transfer, the transaction is considered an export. An item is also considered an export even if it is leaving the United States temporarily, if it is leaving the United States but is not for sale (e.g., a gift), or if it is going to a wholly-owned U.S. subsidiary in a foreign country. Even a foreign-origin item exported from the United States, transmitted or transshipped through the United States, or being returned from the United States to its foreign country of origin is considered an export. Finally, release of technology or source

code subject to the EAR to a foreign national in the United States is "deemed" to be an export to the home country of the foreign national under the EAR.

Who is a Foreign National/Person

The federal definition of a foreign national is a person who is **not**:
- granted permanent U.S. residence, as demonstrated by the issuance of a permanent residence card, i.e., a "Green Card"
- granted U.S. citizenship
- granted status as a "protected person" under 8 U.S.C. 1324b(a)(3), e.g., political refugees, political asylum holders, etc.

This includes all persons in the U.S. as students, business people, scholars, researchers, technical experts, etc.

Note: "Foreign national" is the term used by the Department of Commerce, while "foreign person" is the term used by the Department of State.

What is the Fundamental Research Exclusion

It is possible a license may not be required if the Fundamental Research Exclusion is applicable. Fundamental research is research in science, engineering, and 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. Restrictions on the publication of research results and personnel access restrictions can invalidate the Fundamental Research Exclusion. The Fundamental Research Exclusion applies only to the dissemination of research data and information, not to the transmission of material goods.

Factors to Consider in Determining the Applicability of Export Regulations

The following are factors to consider in determining the applicability of export regulations:
1. Does the activity involve foreign nationals, as defined above?
2. Is the activity considered fundamental research? (Will research results be published and publicly available?)
3. Is the activity limited to teaching or instructional activities?
4. Is there a physical export of a good?
5. Are foreign nationals restricted from participating in the activity?
6. What is the Item's Export Control Classification Number (ECCN) or U.S. Munitions List (USML) category?

7. Where is it going (country)?
8. Who is the end-user (person or entity)? What is the intended end use?
9. Are you screening for persons or entities identified on any lists of sanctioned or barred persons or entities?
10. Is a license required? If so, is enough time allowed to secure one?
11. Will the activity involve a sanctioned or embargoed country?

Those who manufacture civilian items, such as electronics and computer technology, may not be aware that export controls can apply to their goods. Civilian products that have military application are called "dual-use" items. Within the specifications defined in the EAR, these items may require an export license. Controlled goods are identified by either an Export Control Classification Number (ECCN) from the Commerce Control List (CCL) for civilian items, or a U.S. Munitions List (USML) category for military items. The CCL consists of ten categories each with five group types designating dual-use items governed by the EAR. The USML consists of 21 categories outlining goods and technologies applicable to the ITAR. Export controls, when applicable, may require UAMS to receive authorization from the US Government in the form of an export license. An export license permits controlled items to be sent outside of the US, or for controlled information to be shared with foreign persons in the US ("deemed exports").

Export Assessment Process

All UAMS employees must comply with Export Control Regulations. Responsibilities of faculty, staff and students include, but are not limited to:
- Securing the research and technology, chemicals and biological materials handled, and proprietary and Government articles entrusted to individuals against unauthorized use or theft.
- Ensuring that any potential foreign research collaborators and foreign visitors are screened through the Office of Export Control in order to ensure said person is not embargoed or sanctioned. The Office of Export Control utilizes the online Visual Compliance tool, which provides updated information on export control regulations and the ability to search the Commerce Department's Bureau of Industry Standards (BIS) Commerce Control List and the ITAR U.S. Munitions List.,
- Ensuring any physical good or material being shipped or transferred to a foreign country is not on the Commerce Control List (CCL) of the Export Administration Regulations (EAR), unless a license is obtained or a license exemption applies.

Research or Other Activities Undertaken by Foreign Nationals

To assist the Principal Investigator/Sponsor (PI) and UAMS staff, the following process has been developed:

1. The PI responsible for a project will determine whether a project is covered under the Export Control Regulations. Accordingly, to facilitate the determination whether the Export Control Regulations apply to a particular project, the PI is required to complete an online [Export Control Form for Foreign Nationals](#) as part of the immigration process to determine the need for additional review and further actions for a particular project. Consultation with the Office of Institutional Compliance, Director of Export Control may be required and a license from the Department of State or Department of Commerce may be necessary.

2. The Director of Export Control or his designee as an initial matter will screen the foreign national and home institution using the online Visual Compliance tool which provides updated information on export control regulations and the ability to search the Commerce Department's Bureau of Industry Standards (BIS) Commerce Control List and the ITAR U.S. Munitions List.

>   a. The PI will determine, based on the known controlled technologies and the foreign nationals country of origin, in consultation with the Director of Export Control, whether an export license is required. If a license is required, the foreign national shall not be exposed to any controlled technology until a license has been obtained. Licensure may be a condition for a foreign national's employment or affiliation with UAMS.

3. For sponsored projects, the removal of any publication or access provisions in an award document will be negotiated, in order to allow the sponsored project to be conducted as fundamental research, not subject to export control regulations.
>   a. If amending the agreement is not possible, the PI must determine whether or not any foreign nationals (including foreign students) will be involved in any phase of the research.

>   b. If foreign nationals (including foreign students) will be involved, then an export license is required from the relevant federal agency prior to conducting any controlled research activity.

4. A Technology Control Plan (TCP) is required for all research involving data, material, or technology that falls outside the Fundamental Research Exclusion (FRE) due to contractual restrictions, such as publication or foreign national restrictions, or that falls under the authority of the US Department of Commerce's EAR or the US Department of State's ITAR. In these instances, relevant technical information, data, materials, software, or hardware such as technology generated from this project, must be secured from use and/or observation by unlicensed non-U.S. citizens. Security measures will be appropriate to the classification involved. The TCP shall include a physical and information security plan, personnel screening procedures and a process for carrying out the research in a controlled environment. This requirement applies to all research activities whether or not

they are externally sponsored. The Office of Export Control has created a template TCP to serve as a starting point, with the intention that it be adapted to, first and foremost, comply with the specific regulatory requirements and secondly to accommodate the needs and structure of the related UAMS project or program. The form TCP is attached in Appendix A.

International Shipping

UAMS' international shipping must comply with export and import control laws and regulations. The laws and regulations may require UAMS to obtain an export license for shipments of items, software and technology outside of the U.S.

All UAMS personnel who engage in international shipping are responsible for ensuring compliance with U.S. export control laws and regulations. Shipping without obtaining the appropriate license or other government approval, or failing to file accurate export or shipping documentation, may result in the confiscation of the shipped items, fines and/or jail time.

The Director of Export Control will assist you in evaluating if the export is in compliance with export control laws and regulations, and if the export and shipping documentation has been correctly prepared and filed. For items not export controlled, review and clearance to ship may take only a few minutes. For an export controlled item needing a license, it may take 30-90 days to obtain approval from the government. Federal regulations require UAMS to keep records of shipments for five years after the date of the shipment.

Personnel involved with shipping also need to recognize that the destination country for the shipment may have restrictions on what can be imported.

Shipping anything to a destination outside the U.S. is an export regardless of whether the item is sold, used for research, loaned, donated or only outside of the U.S. temporarily. Most items, including certain software and information, are subject to some facet of export controls.

UAMS is the shipper of record regardless of who prepares the forms (FedEx, UPS, DHL or the customs broker). The freight forwarder cannot be relied on for UAMS' export control compliance. The freight forwarder relies on the information provided to them by UAMS.

All items to be exported must be reviewed prior to shipment to determine the need for a license or other government approval. The review includes determining:

- The item(s) export control classification or category;
- If the shipment is to an embargoed or sanctioned country;
- If the shipment to the destination country requires a license;

- The end-user; and
- If the end-use is prohibited.

This review must occur whether the item to be shipped is processed through UAMS Distribution Services or is done by individually by the College, School, Division or Department.

To assist with evaluating the export control issues, please prepare the [Export Control International Shipment Review Form](#) and send to the Office of Export Control for review prior to exporting any item.

International Travel

UAMS faculty, staff and students commonly bring their laptops, cell phones, GPS Devices, PDAs, data storage devices and other electronic devices loaded with information and software ("Devices") with them not only across campus, but also to other countries. Although taking Devices to international destinations or shipping them ahead seems routine, individuals doing so may be "exporting" the Device for purposes of the U.S. export control laws and regulations. Such "exports" may require a license from the U.S. government. Export here is defined as an actual shipment or transmission of items subject to export controls out of the United States, or release of technology or software subject to export controls to a foreign national in the United States. Release of export-controlled technology and source code can also occur through transmission via e-mails, faxes, designs, and verbal correspondence.

Most international travel with Devices (or the shipment of Devices) will not require a license. UAMS travelers should be familiar with the applicable export control regulations, however, and strive to comply, because violations can result in the imposition of criminal sanctions and heavy civil penalties. The Director of Export Control in the Office of Institutional Compliance, is available (in consultation with the Office of General Counsel) to assist UAMS travelers in ascertaining compliance requirements.

The licensing requirements can be summarized generally as follows:

Travelers will most likely not need a license to take or ship any Device outside the United States if all of the following apply:

- If the Device is a standard, off-the-shelf product widely available to the public.

- All data and information stored on the Device is publically available (such as through academic publications or presentations at conferences or tradeshows) or resulted from fundamental research.

• Travel is not to a country subject to export control embargoes: Cuba, Iran, Syria, Sudan or North Korea.

Travelers are likely to require an export license to bring a Device outside the United States if:

• The Device holds encryption software, either commercially available or research-generated;

• The Device contains unpublished data or other information relating to items or materials on one of the technology control lists established by the U.S. government (An example of such information would be blueprints of laboratory equipment that could be used to create toxic materials.). Note that the need for an export license would probably not apply to data and information which resulted from fundamental research: basic and applied research typically associated with academia where the resulting information is ordinarily published and shared broadly in the scientific community;

• The Device is designed for use or application with technologies associated with satellites, spacecraft or technologies with a military use, or the Device contains information or software designed for use or application with such technologies; or

• The Device could be used in the development of weapons of mass destruction.

Travelers should not take or ship any Device outside of the United States without review and approval by the Office of Export Control, if any of the following apply as a license will most likely be required:

• The travel or shipment is to Cuba, Iran, Syria, Sudan or North Korea

• The Device is an ITAR-Controlled article, software or technical data. ITAR controlled articles, software and technical data are directly related to military uses, satellites or spacecraft.

One important exception to the need for a license is the "Tools of Trade" license exception. This would apply when all of the following apply to a Device:

• Hand-carried with the individual while traveling,

• Carried in the luggage or baggage that travels with the individual, or

• Shipped no more than thirty days prior to the individual's departure or may be shipped to the individual at any time while the individual is outside the country.

Generally, so long as the Traveler retains his or her Device under their personal custody and effective control for the duration of travel; (2) does not intend to keep these items outside the U.S. for longer than 1 year; and (3) the individual is not traveling to an embargoed country, no government export license is required. Note that this license exception is not available for equipment, components, or software designed for use in/by/with most satellites or spacecraft. "Effective control" means retaining physical possession of an item or maintaining it in a secure environment.

In addition to becoming familiar with applicable export control requirements, UAMS travelers should note that any international travel with a Device may result in the disclosure of personal information installed on the Device. In some countries, custom officials may examine information contained in Devices or seize Devices. Instances of laptop seizures have been widely reported in the press. Travel in and out of the U.S. is no exception: Homeland Security personnel may inspect information contained in a traveler's Device, or seize the Device. UAMS travelers should therefore consider carefully which Devices, bearing what information; they wish to bring with them on international trips.

Individuals traveling on UAMS business must complete the International Travel Form and should complete any applicable license exemption document, also available on the UAMS website, prior to international travel. If you have any questions or need more detailed information about this topic, please contact the Director of Export Control.

See also Guidance from the Federal Bureau of Investigations for international travel:

[Safety and Security for the Business Professional Traveling Abroad](#)

[Safety and Security for U.S. Students Traveling Abroad](#)

Applying for an Export License

UAMS in conjunction with the PI or other applicable party will make the business decision on whether to request a federal license. If there is a decision to move forward with the request, the Office of Institutional Compliance, Director of Export Control will work with the requestor to complete all necessary documentation and submit the license to appropriate federal agency involved. SNAP-R is the Internet portal used to submit license applications, advisory opinions, and ECCN classification requests. When applying for a license through SNAP-R, the PI must submit the following:

    (1) a comprehensive biography for the researcher;

    (2) an accurate description of anticipated work duties;

(3) a letter of explanation as to the nature of the research;

(4) a copy of all available immigration documents;

(5) abstracts for any related published materials; and

(6) a technology control plan, which must explain:

    (a) a statement of UAMS' commitment to export compliance;

    (b) a physical security plan;

    (c) an information security plan;

    (d) personnel screening procedures;

    (e) explanation of export control training and awareness programs; and

    (f) details of internal audit programs.

Once an application has been successfully processed, a copy of the license will be maintained by the Director of Export Control and copies will be given to affected persons. Deemed export licenses are specific not only to persons, but also to access and activities. If any substantive change in the working environment or duties is anticipated, the licensee must contact the Director of Export Control to discuss whether a new license must be obtained.

Oversight and Violations

If a violation, real or perceived, of the Export Control Regulations occurs during the course of a project, it must be brought to the attention of the immediate supervisor and Office of Institutional Compliance, Director of Export Control immediately. Once an alleged violation has been reported, an investigation will be initiated to determine the validity of the allegation and an appropriate response. If the allegation merits further fact finding and investigation, Director of Export Control will work with the appropriate parties to conduct a thorough investigation. The goal for completing any investigation is 120 days from the date of initiation. Any results will be made known to senior management to consider further action, including, after consultation with the Office of General Counsel, self-disclosure to the appropriate federal government agency and corrective action. All documents and records relating to any suspected violation must be immediately secured and maintained in accordance with all applicable record keeping requirements. Information Technology and Campus Police will support these investigations as needed. No employee shall be punished solely on the basis that he or she reported what was reasonably believed to be an act of wrongdoing or a violation of the export control laws.

Training

Training is a critical component to maintaining compliance with export control laws. The primary goal of training is to increase awareness of and maintain compliance with export control laws and trade sanctions. It is especially critical that faculty and administrative staff with export controlled activities participate in training. Training on Export Control Regulations is offered by UAMS via the use of the CITI Program Export Controls Training Module. The training consists of an export control overview, a review of the EAR and ITAR regulations and OFAC requirements. Additionally, live training sessions are provided periodically or as requested.

Penalties

UAMS is required to demonstrate its export control due diligence and to document its adherence to US export controls and trade sanctions laws. There are severe civil and criminal penalties, including fines and imprisonment, for violating the export control laws and trade sanctions and both the organization and the individuals involved are subject to these penalties. Criminal violations of violations of EAR carry potential penalties of the greater of $50,000-$1,000,000 or five time the value of the export, as well as up to 10 years imprisonment; civil penalties include fines of $10,000-$120,000. Criminal violations of ITAR can entail fines of up to $1,000,000 and up to 10 years' imprisonment; civil penalties include fines of up to $500,000. Criminal violations of OFAC are also severe. UAMS and the individual(s) involved may also lose their ability to export. UAMS may be suspended or debarred from government contracting.

Record Keeping

All records related to export controls, whether actual licenses or documentation supporting a decision that no license is required, must be maintained for 5 years, in accordance with the UAMS Administrative Guide, 3.2.01 Record Retention.

Appendix A

University of Arkansas for Medical Sciences

Requirement for a Technology Control Plan

A Technology Control Plan (TCP) is required for all research involving data, material, or technology that falls outside the Fundamental Research Exclusion (FRE) due to contractual restrictions, such as publication or foreign national restrictions, or that falls under the authority of the US Department of Commerce's Export Administration Regulations (EAR) or the US Department of State's International Traffic in Arms Regulations (ITAR). The US Department of Treasury's Office of Foreign Asset Control (OFAC) is responsible for administering and enforcing economic and trade sanctions against certain nations, entities, and individuals if there is a violation.

Under the EAR and ITAR, it is illegal to send or take Export-Controlled items or information out of the U.S. This includes disclosing information orally or visually, or transferring export-controlled items or information to a foreign person inside or outside the U.S. without proper approval. Under the ITAR or the EAR, an export license may be required for foreign nationals to access export-controlled information. A foreign person is a person who is not a U.S. citizen or permanent resident alien of the U.S., or not a documented refugee in the U.S. as a protected political asylee or under amnesty. The law makes no exceptions for foreign students.

Relevant technical information, data, materials, software, or hardware such as technology generated from this project, must be secured from use and/or observation by unlicensed non-U.S. citizens. Security measures will be appropriate to the classification involved.

The TCP shall include physical and information security plans, personnel screening procedures, and a process for carrying out the research in a controlled environment. This is a basic template for minimum elements of a TCP.

The TCP should specifically address the following:

A) Personnel Training - Awareness and basic understanding of export restrictions; document time and date of training. *NOTE: All laboratory personnel should receive basic training.*

B) Personnel Screening - Identity of foreign nationals with physical access to the laboratory area; identity, residency status, and project role of UAMS participants; identity of person with primary responsibility for security of controlled items/materials/equipment (usually the Principal Investigator but may be a senior member of the research team).

C) Physical Security - Laboratory and building access, escort requirements, visitor logs, etc.

D) Equipment Access - Identification of controlled laboratory equipment and methods for restricting access.

E) Information Security - Control of access to both electronic and physical data and information, software, and prototype.

F) Internal security evaluation - Periodic review and audit of internal controls to identify and report findings of any unauthorized export.

G) Statement that participants are not on any of the following lists:

- Denied Persons List
- Unverified List
- Entity List
- Specially Designated Nationals List
- Debarred List

H) Statement that a) controlled items have been or will be identified for all participants prior to allowing access; b) all participants having access to controlled items have been informed of the security measures to be used in controlling access; c) participants will be adequately supervised by the person responsible for access control to prevent the export to unauthorized persons.

I) Signature of Principal Investigator and, if different, the person with primary responsibility for access control.

J) Signature of Department Head/Chair or Institute Director acknowledging approval to engage in controlled research activities as described.

Technology Control Plan

Statement of Institutional Commitment: UAMS is committed to complying with applicable export control, embargo and trade sanction laws and regulations in all UAMS activities. This commitment is articulated in the UAMS policy on Export Controls and the associated Export Control Management Program. This Technology Control Plan (TCP) identifies the specific measures that will be taken by all project personnel to ensure compliance with those requirements.

Principal Investigator _____

Phone: _____ Email: _____

Campus Address: _____

Locations Covered By Plan: Building(s) _____ Room(s) _____

_____ _____

_____ _____

Sponsor (if applicable) _____

Cost Center Number (if known) | Project Period | Start | End

| | |
| ____ | ____ |

Contractual Obligations/Restrictions   ☐ Yes   If Yes, describe
   ☐ No

Non-Disclosure Agreement   ☐ Yes   If Yes, parties to agreement: _____
   ☐ No

Attachments. Describe in detail the following steps taken to prevent the release of controlled items/information.

A.   Personnel Screening and Training   D.   Physical Security

B.   Physical Access   E.   Information Security (including computer access)

C.   Internal Security Evaluation

Certification:

By signing below, I certify I am committed to the protection of controlled items in accordance with U.S. export regulations and that the statements contained herein are accurate and truthful to the best of my knowledge and belief. I further certify that a) controlled items have been or will be identified for all participants prior to allowing access; b) all participants having access to controlled items will receive basic training in U.S. export regulations and be informed of the security measures to be used in controlling access to project information prior to access, and c) all participants will be adequately supervised by me, the Principal Investigator, or by the person designated the primary responsibility for access control if other than myself.

I have verified that no personnel working on this project are on any of the following Lists: a) Denied Persons, b) Unverified, c) Entity, d) Specially Designated Nationals, and e) Debarred/Suspended.

_____   _____

Principal Investigator   Date

_____   _____

Designated Control Person (if other than Principal Investigator)   Date

_____   _____

Department Head/Chair or Equivalent   Date

Export Control Plan Attachments

Principal Investigator:		
Project Title:		
A.	Personnel Screening and Training:	
B.	Equipment Access:	
C.	Internal Security Evaluation:	
D.	Physical Security:	
E.	Information Security:	