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Navigating Export Control Laws in Animal Research: Key Considerations

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ABOUT THE EXPORT CONTROLS OFFICIAL

All academic institutions which perform fundamental or restricted research must demonstrate that they have a system in place to identify and mitigate export control compliance risk. The 2007 U.S. Sentencing Commission Guidelines at Section 8B2.1 requires academic institutions to have an export controls program with the following elements:

- Standards and Procedures
- Governance, Organization, and Reporting
- Assignment of Substantial Authority
- Training and Education
- Monitoring and Auditing, Program Assessment, & Helpline
- Consistent Enforcement and Discipline
- Responses to Noncompliance and Program Modifications

Institutions often adopt a simple and effective way to manage export control compliance risk by identifying a single individual with overall responsibility for export control compliance on campus. The appointed official (Export Control Official or Export Control Officer) will be responsible for export control and serve as the point of contact for all export control questions or issues. The office or designee is granted "substantial authority" to make independent decisions void of organizational conflicts of interest. The official should have direct reporting lines to the university's executive level. If the University is registered under ITAR, subject to 22 CFR 120-130, an Empowered Official with sufficient authority to verify accuracy of transactions is necessary.

Introduction

Animal research has a vital role in advancing scientific knowledge, medical breakthroughs, and innovations. The cutting-edge research with animal models often involves the use of controlled materials, advanced technologies, and technical information that may have potential dual use and thus falls under export control regulations. Items classified under dual use can be used both for civilian and military applications and often weaponized or worse, used for terrorism. Forge (2010)[2] identifies dual use as having three distinct parts – three related kinds of things comprise the category of dual use: research, technologies, and artefact. Thus, it is possible that common or innocuous items used in laboratory or animal welfare can require export controls oversight. Navigating export control laws falls under biosecurity and use of biological materials in animal research requires a thorough understanding of the regulations, compliance procedures, and potential implications.

The export control regulations are designed to safeguard national security, protect sensitive technologies, and prevent the unauthorized sharing of controlled items with foreign entities. Export control laws are implemented by governments to regulate the transfer of certain items, technologies, and information to foreign individuals or entities. Many federal agencies are involved in implementing the regulations that are considered critical to national security and may cover a wide range of items, including equipment, biological materials, chemicals, software, and technologies used in animal research. Researchers involved in animal studies must be aware of potential export-controlled elements in their projects, as non-compliance can lead to severe legal and financial consequences. In many institutions, the researcher is responsible for initial determination of the applicability of export control regulations.

An Overview of Export Control

There are three U.S. government agencies that control the majority of exports: the Department of Commerce, the State Department, and the Treasury Department. By far the biggest regulatory body is the Department of Commerce - especially the Bureau of Industry and Security (BIS) which implements and enforces the Export Administration Regulations (EAR), which lists products under the Commerce Control List (CCL). Depending on the nature of research, Department of Defense Trade Controls (DDTC) which enforces International Traffic in Arms Regulations (ITAR) might be applicable. Other agencies that may have oversight over animal activities include USDA, U.S. Fish and Wildlife Service, USPS, and Customs and Border protection. There is not a single agency or department that regulates all U.S. exports. Institutions must be aware of the various regulations and have documented processes that ensure that compliance is always maintained.

In addition, institutions are responsible for safe-guarding select agents, which are bacteria, viruses, toxins, or other biological agents and substances that pose a severe threat to public health and safety if they are accidentally released. The U.S. government maintains a list of select agents and toxins that are subject to special restrictions and oversight when it comes to possessing, using, storing, or transferring. All select agents are subject to strict export controls and are regulated through the following agencies:

- The Centers for Disease Control and Prevention (CDC) regulates the possession, use, and transfer of biological select agents and toxins that have the potential to pose a severe threat to public health and safety. The CDC maintains a list of select agents and toxins that fall under these oversight regulations.
- The Animal and Plant Health Inspection Service (APHIS) provides oversight for the export of certain plant pathogens and livestock/animal pathogens. They maintain a list of regulated plant pests and animal pathogens.
- The Department of Commerce regulates the export of dual-use microorganisms through the Commerce Control List. Dual-use items are those with both commercial and military applications.

In addition to the select agent lists, other microbes like those that cause severe human disease (even if not on the select agent lists) or that could be used to manufacture biological weapons may require export licenses from the CDC, APHIS, or Commerce Department. Strict permitting and registration processes must be followed for exportation. These controls aim to prevent restricted microbes from falling into the wrong hands and threatening public health or national security. Given the layers of oversight required and the large number of microbes, the U.S. Department of Commerce has issued an Export Control Classification Number (ECCN; a 5 character alpha-numeric designation) to identify dual-use items for export controls purposes. Your export controls officer will be able to provide you with the internal screening process at your institution.

Figure 1. Depicts the generalized steps to follow for compliance with export controls regulations.

Export Controls for Biological Organisms

ECCN 1353 applies to genetically modified organisms that contain, or have any genetic element that codes for any gene, genes, translated product, or translated products specific to any virus controlled by 1C351.a or .b [5] or **1C354.c**[5]; any gene or genes specific to any bacterium controlled by **1C351.c**[5] or **1C354.a**[5], or any fungus controlled by **1C351.e**[5] or **1C354.b**[5], and any toxins, or their subunits, controlled by **1C351.d**[5]. If your institution creates or generates genetically modified organisms, including organisms in which the nucleic acid sequences have been created or altered by deliberate molecular manipulation, export controls may be required. ECCN 1354 a, b, c, d, e covers a plant pathogen list that includes bacteria, fungi, and viruses.

If you have federally funded studies that include the creation of genetically modified organisms or working with select agents, a Biosecurity/Technology Control Plan (B/TCP) may be required to prevent unauthorized access by foreign nationals to technology or biologicals controlled for export under the BIS, International Traffic in Arms Regulations (ITAR), or the Export Administration Regulations (EAR). Under export control laws, access to some of these materials is considered as deemed export. The creation of a B/TCP sets forth the security measures that the department, principal investigator, and project personnel agree to implement in the performance of this project to prevent unauthorized foreign persons from gaining access to controlled technologies. For federally funded studies with international collaborations, it is best to consult with an export controls officer before sharing any item, technology, or information. The institution must obtain necessary licenses or use appropriate communication channels to avoid violations.

Shipments

Shipping of all live animals, which includes semen, ovules, and embryos, to foreign countries are considered as export. The export control regulations apply to the final destination and sending animals to most destinations requires license from APHIS[3] and other agencies. The regulatory framework for export controls takes into consideration a detailed look at the context by including questions about –

- Who*'s exporting and who is receiving it?*
- What*'s being exported?*
- When *is the export taking place and how often*?
- Where *is the final destination of the animal*?
- Why *are you exporting the animal*?
- How *is this export being facilitated*?

Because the list of items and countries are long and complex, the Export Administration Regulations (EAR) has created the Entity list[6] of names of certain foreign persons – including businesses, research institutions, government and private organizations, individuals, and other types of legal persons – that are subject to specific license requirements for the export, re-export, and/or transfer (in-country)

of specified items. Additionally, BIS maintains an Unverified List (UVL)[7] of parties that are ineligible to receive items subject to the Export Administration Regulations (EAR) may be allowed to receive live animals by means of a license exception. Exporters must file an Automated Export System record for all exports to parties listed on the UVL and obtain a statement from such parties prior to exporting, re-exporting, or transferring to such parties any item subject to the EAR. Countries subject to embargoes or sanctions have additional regulations, and even sharing non-controlled information might be considered a violation.

If you are shipping animals to international destinations or receiving animals from other countries, it is crucial to pay meticulous attention to detail to ensure compliance with export control laws (see Figure 1 for an outline). Researchers must be proactive in identifying export-controlled elements within their projects and take necessary steps to obtain licenses, authorizations, and approvals. When institutions fail to comply with export controls, it can result in legal penalties, damage to reputation, and potential harm to national security. By fostering a culture of awareness and adherence to export control regulations, researchers can contribute to both scientific advancements and the safeguarding of sensitive technologies. As the landscape of export controls evolves, researchers must remain vigilant and adapt their practices to ensure responsible and lawful animal research. Simple steps and consistency can go a long way to ensure that your animal research is compliant and protected.

If you are interested to know more about the enforcement aspects of export controls in animal research, here are some case studies pertaining to biosecurity.

1. Export of Human Pathogen[4]: A researcher violated regulations when he exported the human pathogen *Yersinia pestis* (also known as the Plague) to Tanzania without the required U.S. Department of Commerce license.
2. Stem Cell Research[1] and indictment text[9]: Three researchers were charged in a two-count superseding indictment with knowingly and willfully conspiring to violate the Iranian Transactions and Sanctions Regulations (ITSR), in violation of 50 U.S.C. § 1705 and 31 C.F.R. §§ 560.203 and 560.204, and knowingly and willfully attempting to export biological items from the United States to Iran without first obtaining the required authorization from the United States Department of Treasury's Office of Foreign Assets Control (OFAC), in violation of 50 U.S.C. § 1705, 31 C.F.R. §§ 560.203, 560.204, and 18 U.S.C. § 2.
3. Lying on NIH Grant[8]: A rheumatology professor with strong ties to China was sentenced to 37 months in prison for making false statements to federal authorities as part of an immunology research fraud scheme. The researcher was also ordered to pay more than $3.4 million in restitution to the National Institute of Health (NIH) and approximately $413,000 to the university.

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