EXPORT REGULATIONS AND BIOLOGICS

CAMPUS COMPLIANCE
BIOLOGICS

• What entities regulate biologics?
• What are the categories of biologics?
• What do I need to know about using biologics on campus?
• What do I need to know about using biologics in my laboratory for research?
• What do I need to do before I ship biologics off campus?
FEDERAL AGENCIES

- **Health and Human Services/Center for Disease Control (HHS/CDC) - Select Agents List** - regulates agents that pose threats to public health and safety in accordance with Part 73 of Title 42, Code of Federal Regulations (Select Agent Regulations).

- **United States Department of Agriculture/Animal and Plant Health Inspection Service (USDA/APHIS) - Select Agents List** - regulates agents that pose a threat to animal and plant health or products in accordance with Part 73 of Title 42, Code of Federal Regulations (Select Agent Regulations).

- **Department of State/Directorate of Defense Trade Controls (DoS/DDTC)** regulates the export of biological agents or biologically derived substances pursuant to the International Traffic in Arms Regulations (ITAR).

- **Department of Commerce/Bureau of Industry and Security (DoC/BIS)** regulates the export of commercial and dual use biologics pursuant to the Export Administration Regulations (EAR).

- **Department of Treasury/Office of Foreign Assets Controls (OFAC)** administers sanctions programs.

- **U.S. Food and Drug Administration (FDA)** authority to authorize the use of Select Agents in Investigational New Drug application (IND), Investigational New Animal Drug file (INAD), or Investigational Device Exemption application (IDE).

- **Federal Bureau of Investigation (FBI)** background clearance as mandated under the USA Patriot Act Select Agent Requirements.

- **Department of Transportation (DoT)** Hazardous Materials Regulations and Transportation Regulations.
SELECT AGENTS REGULATIONS

Regulated by:  HHS/CDC and USDA/APHIS

Select Agents:  Pathogens and toxins determined to have the potential to pose a severe threat to both human and animal health, to plant health, or to animal and plant products.

Examples:
- Yersina pestis
- Bacillus anthracis
- Henda virus
- Francisella tularensis

Complete list can be found at:  www.selectagents.gov/Select%20Agents%20and%20Toxins%20List.html
UNITED STATES MUNITIONS LIST “USML”

Department of State

Administered by: Directorate of Defense Trade Controls “DDTC”

Regulations: International Traffic in Arms Regulations “ITAR”

Controlled Items: United States Munitions List “USML”

Applies to: Defense Articles, Defense Services, and Technical Data
(b) Biological agents and biologically derived substances specifically developed, configured, adapted, or modified for the purpose of increasing their capability to produce casualties in humans or livestock, degrade equipment or damage crops.

(2) The biological agents or biologically derived substances in paragraph (b) of this category are those agents and substances capable of producing casualties in humans or livestock, degrading equipment or damaging crops and which have been modified for the specific purpose of increasing such effects. Examples of such modifications include increasing resistance to UV radiation or improving dissemination characteristics. This does not include modifications made only for civil applications (e.g., medical or environmental use).

(h) Medical countermeasures, to include pre- and post-treatments, vaccines, antidotes and medical diagnostics, specifically designed or modified for use with the chemical agents listed in paragraph (a) of this category and vaccines with the sole purpose of protecting against biological agents identified in paragraph (b) of this category. Examples include: barrier creams specifically designed to be applied to skin and personal equipment to protect against vesicant agents controlled in paragraph (a) of this category; atropine auto injectors specifically designed to counter nerve agent poisoning.
(f) Equipment and its components, parts, accessories, and attachments specifically designed or modified for military operations and compatibility with military equipment as follows:

1. The dissemination, dispersion, or testing of the chemical agents, biological agents, tear gases and riot control agents, and defoliants listed in paragraphs (a), (b), (d), and (e), respectively, of this category;

2. The detection, identification, warning, or monitoring of the chemical agents and biological agents listed in paragraph (a) and (b) of this category;

3. Sample collection and processing of the chemical agents and biological agents listed in paragraph (a) and (b) of this category;

4. Individual protection against the chemical agents and biological agents listed in paragraphs (a) and (b) of this category. This includes military protective clothing and masks, but not those items designed for domestic preparedness (e.g., civil defense);

5. Collective protection against the chemical agents and biological agents listed in paragraph (a) and (b) of this category.

6. Decontamination or remediation of the chemical agents and biological agents listed in paragraph (a) and (b) of this category.

(g) Antibodies, polynucleoïdes, biopolymers or biocatalysts specifically designed or modified for use with articles controlled in paragraph (f) of this category.
(i) Modeling or simulation tools specifically designed or modified for chemical or biological weapons design, development or employment. The concept of modeling and simulation includes software covered by paragraph (m) of this category specifically designed to reveal susceptibility or vulnerability to biological agents or materials listed in paragraph (b) of this category.

(j) Test facilities specifically designed or modified for the certification and qualification of articles controlled in paragraph (f) of this category.

(k) Equipment, components, parts, accessories, and attachments, exclusive of incinerators (including those which have specially designed waste supply systems and special handling facilities), specifically designed or modified for destruction of the chemical agents in paragraph (a) or the biological agents in paragraph (b) of this category. This destruction equipment includes facilities specifically designed or modified for destruction operations.

(l) Tooling and equipment specifically designed or modified for the production of articles controlled by paragraph (f) of this category.

(m) Technical data (as defined in § 120.10 of this subchapter) and defense services (as defined in § 120.9 of this subchapter) related to the defense articles enumerated in paragraphs (a) through (l) of this category. (See § 125.4 of this subchapter for exemptions.) Technical data directly related to the manufacture or production of any defense articles enumerated elsewhere in this Category.
COMMODITY CONTROL LIST “CCL”

Department of Commerce

Administered by: The Bureau of Industry and Security “BIS”

Regulations: Export Administration Regulations “EAR”

Controlled Items: Commodity Control List “CCL”

Applies to: Commercial and “dual use” (commercial and military/security applications) commodities, technology, and software.
COMMERCIAL AND “DUAL USE”

1C351 Human and zoonotic pathogens and toxins
Examples: Hantann virus, monkey pox virus, bacillus anthracis, yersinia pestis, conotoxin,

1C352 Animal pathogens
Examples: African swine fever virus, lyssa virus, foot and mouth disease virus

1C353 Genetic elements and genetically-modified organisms

1C354 Plant pathogens
Examples: Xanthomonas, cochliobolus miyabeanus, Andean potato latent virus

IC360 Select agents list

IC991 Vaccines, immunotoxins, medical products, diagnostic and food testing kits
Examples: vaccines for items controlled and immunotoxins, medical products and diagnostic food testing kits for some items controlled
COMMERCIAL AND “DUAL USE”

1E001 “Technology” for development or production of items listed in 1C

1E351 “Technology” for the disposal of chemical or microbiological materials

2B352 Equipment capable of use in handling biological materials

Examples: some fermenters, centrifugal separators, cross (tangential) flow filtration equipment, accessories, and components, class III biologic safety cabinets, chambers designed for aerosol challenge testing, protective equipment

2E001 “Technology” for the development of equipment or software controlled by 2B

2E002 “Technology” for the production of equipment controlled by 2B

2E301 “Technology” for the use of items controlled in 2B352

“Technology”. (General Technology Note)-- Specific information necessary for the “development”, “production”, or “use” of a product. The information takes the form of “technical data” or “technical assistance”.

“Use”. (All categories and General Technology Note)--Operation, installation (including on-site installation), maintenance (checking), repair, overhaul and refurbishing.
Commercial items not included on the CCL are designated and generally may be exported without a license “EAR99”

**BUT REQUIRE A LICENSE** when exported to Cuba, Syria, Sudan, Iran, and North Korea or end users/end uses of national security/foreign policy concerns.
RECEIVING BIOLOGIC MATERIALS

Questions to consider prior to receiving biologics on campus:

• Is your laboratory registered with Environmental Health & Safety?

• Does your laboratory have the proper security controls for the materials/equipment or technical data you will be receiving?

• Do you need additional agency approvals?

• Do any of your research staff need clearance by a federal agency to work with the materials?

• Do I need to notify any campus offices?

Contact Environmental Health and Safety for additional guidance on receiving biologics on campus:

http://www.stonybrook.edu/ehs/
IS MY RESEARCH STUDY SUBJECT TO EXPORT CONTROLS?

• What is my responsibility to knowing who I am including in my research?
• Are the results of my research subject to export controls?
• Are the materials/equipment that I am using to conduct my research subject to export controls?
• Is the technical data about the materials/equipment that I am using to conduct my research subject to export controls?
• Are the materials/equipment/technical data that I am sending abroad subject to export controls?
• Are the materials/equipment or technical data about the materials/equipment that I am sending to another US collaborator/subcontractor subject to export controls?
KNOW WHO YOU ARE DEALING WITH

What is my responsibility to knowing who I am including in my research?

Various government lists of entities that need to be checked to ensure that you are not dealing with a denied or debarred party.

- Department of Commerce, Bureau of Industry and Security Denied Persons List (DPL)
- Department of Commerce, Bureau of Industry and Security Entity List (EL)
- Department of Commerce, Bureau of Industry and Security Unverified List (UL)
- Department of Treasury, Office of Foreign Assets Control (OFAC) list of Specially Designated Nationals and Blocked Persons (SDN List)
- Department of State, Bureau of International Security and Nonproliferation list of parties sanctioned for various reasons
- Department of State, Directorate of Defense Trade Controls list of debarred individuals
ITEMS NOT SUBJECT TO THE ITAR

Are the results of my research subject to export controls? Items not subject to ITAR

Public domain (22 CFR 120.11)

- **Information** which is published and which is generally accessible or available to the public:
  - Through sales at newsstands and bookstores;
  - Through subscriptions which are available without restriction to any individual who desires to obtain or purchase the published information;
  - Through second class mailing privileges granted by the U.S. Government;
  - At libraries open to the public or from which the public can obtain documents;
  - Through patents available at any patent office;
  - Through unlimited distribution at a conference, meeting, seminar, trade show or exhibition, generally accessible to the public, in the United States;
  - Through public release (unlimited distribution) after approval by the cognizant U.S. government department or agency;
  - Through **fundamental research** in science and engineering at accredited institutions of higher learning in the U.S. where the resulting information is ordinarily published and shared broadly in the scientific community.
ITEMS NOT SUBJECT TO THE EAR

Are the results of my research subject to export controls? Items not subject to EAR

- Published **Information** and Software (15 CFR 734.7)

- **Information** Resulting from Fundamental Research (15 CFR 734.8)

- Educational **Information** (15 CFR 734.9)

- **Information** included in certain patent applications (15 CFR 734.10)
INFORMATION RESULTING FROM FUNDAMENTAL RESEARCH

Basic and applied research in science and engineering, where the resulting information is ordinarily published and shared broadly within the scientific community.

• Research conducted by scientists, engineers, or students at a university normally will be considered fundamental research;

• Prepublication review by a sponsor to insure that proprietary information is not divulged does not change the status of the research;

• Prepublication review by a sponsor to ensure that the publication would not compromise patent rights does not change the status of the research.
WHEN IS IT NOT FUNDAMENTAL RESEARCH?

• Release of information from a sponsor to the university where the research results are subject to prepublication review AND/OR initial transfer of information from a sponsor to the university where they have agreed that the sponsor may withhold information from publication ARE SUBJECT TO THE EAR.

• NOT FUNDAMENTAL RESEARCH if university accepts restrictions on publication or accepts specific security controls as part of a research project or activity sponsored by the U.S. government.

• Proprietary research, industrial design, production, and product utilization, the results of which ordinarily are restricted for proprietary reasons or specific national security reasons.
DEEMED EXPORTS: TECHNICAL DATA

ITAR

Sending or taking a defense article out of the U.S.;

Disclosing (including visual or oral) or transferring in the U.S. any defense article to a foreign embassy or agency of a foreign government;

Disclosing (including visual or oral) or transferring technical data to a foreign person, whether in the U.S. or abroad;

Performing a defense service on behalf of, or for the benefit of, a foreign person, whether in the U.S. or abroad.

EAR

Actual shipment or transmission of items subject to the EAR out of the U.S., or

The release of technology or software subject to the EAR to a foreign national in the U.S. (“Deemed Export”)

Through:
Visual Inspection
Oral Exchange
Electronic/Digital Exchange
Available by Practice/Application (e.g. training)
FOREIGN NATIONAL ACCESS

International Traffic in Arms Regulations – United States Munitions List

Foreign nationals on campus may NOT access ITAR controlled items and technical data, including biological agents or biologically derived substances, without a license or exemption.

There is an Employment Exemption, however, this is very narrowly defined and requires documentation (method of qualifying exemption and written notification to the foreign national employee) and these documents must be retained according to federal record keeping regulations.
FOREIGN NATIONAL ACCESS

Export Administration Regulations – Commodity Control List

Foreign nationals on campus may access EAR controlled items and technical data, including biological agents or biologically derived substances, without a license under specific situations.

1. You are conducting fundamental research; and

2. None of the 5 main technology ECCNs are applicable to your research.
   1E001 “Technology” for development or production of items listed in 1C
   1E351 “Technology” for the disposal of chemical or microbiological materials
   2E001 “Technology” for the development of equipment or software controlled by 2B
   2E002 “Technology” for the production of equipment controlled by 2B
   2E301 “Technology” for the use of items controlled in 2B352

Special Note: Company proprietary information released to the university with the condition of not releasing the information to the public may be subject to export regulations even if the project is for fundamental research!
EXPORTING MATERIALS, EQUIPMENT, AND TECHNICAL DATA ABROAD

ITAR

Sending or taking a defense article out of the U.S.;

Disclosing (including visual or oral) or transferring in the U.S. any defense article to a foreign embassy or agency of a foreign government;

Disclosing (including visual or oral) or transferring technical data to a foreign person, whether in the U.S. or abroad;

Performing a defense service on behalf of, or for the benefit of, a foreign person, whether in the U.S. or abroad.

*Can not be exported without a license or exemption

EAR

Actual shipment or transmission of items subject to the EAR out of the U.S., or

The release of technology or software subject to the EAR to a foreign national in the U.S. (“Deemed Export”)

*The need for a license is dependent upon several factors
SHARING/SENDING EXPORT CONTROLLED MATERIALS, EQUIPMENT, TECHNICAL DATA WITHIN THE US

When sending these items to a US collaborator/subcontractor, need to consider:

Who? Are they on a federal list?

Why? Does the party have a legitimate use for materials/equipment/technical data that they will be receiving?

Permission? Do you need to get permission from another federal agency to transfer these materials?
SENDING MATERIALS

Questions to consider prior to sending biologics off campus:

• Do I need to notify any campus offices?

Several campus offices might be involved in a shipment of biologics off campus, this could include Environmental Health & Safety, Office of Technology Licensing and Industry Relations, and/or Office of Research Compliance

• Do I need specialized training from Environmental Health & Safety?

• Do I need permission from HHS/CDC or USDA/APHIS?

• Do I need to verify that the receiver has the appropriate clearances and/or security for the materials I am sending?

Contact Environmental Health & Safety for additional guidance specific to the biologics you will be shipping

• Do I need a Material Transfer Agreement?

Contact the Office of Technology Licensing and Industry Relations for additional guidance specific to the biologics you will be shipping

• Do I need an Export License?

Contact the Office of Research Compliance for additional guidance specific to the biologics you will be shipping
A Material Transfer Agreement (MTA) is required anytime a researcher ships any novel or proprietary material or information to a collaborator at an outside institution.

Material Transfer Agreements are simple documents that convey the following to the receiving party:

- What the material is;
- Who created and owns the material;
- How to credit the Stony Brook University Faculty member in any publications resulting from the use of the material; and
- Who is responsible for any issues that may arise from the use of the materials.
DO I NEED A LICENSE TO EXPORT?

ITAR - United States Munitions List Items and Technical Data:

NO article on the USML can be exported (sent or taken) without a license or exemption.

EAR - Commodity Control List Items and Technical Data:

Licensing requirements for items and technical data on the CCL depend on the answers to the following questions:

- WHAT - the ECCN classification
- WHERE - the destination
- WHO - the end user
- WHY - the end use
ADDITIONAL RESOURCES

Government Websites:

Export Administration Regulations: http://www.bis.doc.gov/index.php/regulations/export-administration-regulations-ear

International Traffic in Arms Regulations: http://www.pmddtc.state.gov/regulations_laws/itar.html

National Select Agent Registry: www.selectagents.gov/Select%20Agents%20and%20Toxins%20List.html

Stony Brook University Websites:

Environmental Health & Safety: http://www.stonybrook.edu/ehs/


Office of Technology Licensing & Industry Relations: http://www.stonybrook.edu/research/otliir/index.shtml
CAMPUS ASSISTANCE

Campus Compliance:
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