



System-wide Policy: Export Controls and Economic Sanctions for Research

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Approved By: Ethics and Compliance Oversight Committee

System-wide Policy Ownership Group: Research Compliance
System-wide Policy Information Resource: Director of Research Compliance

Stakeholder Groups
Research Administration
Research Directors
Human Research Protection Program
Allina Health Lab
Research Privacy

SCOPE:

Sites, Facilities, Business Units	Departments, Divisions, Operational Areas	People applicable to:
Allina Health Group, Abbott Northwestern Hospital, Buffalo Hospital, Cambridge Medical Center, District One Hospital, Mercy Hospital, New Ulm Medical Center, Owatonna Hospital, Phillips Eye Institute, Regina Hospital, River Falls Area Hospital, St. Francis Regional Medical Center, United Hospital, all other Business Units	All	All persons performing research at Allina Health.

POLICY STATEMENT: Allina Health is committed to complying with U.S. Export Control Laws and Economic Sanctions. All persons performing research at Allina Health will conduct their activities in accordance with U.S. Export Control Laws and Economic Sanctions. These Laws and Economic Sanctions protect U.S. national security, promote U.S. foreign policy objectives, and further U.S. economic interests. It is a violation of this policy to engage in any activity that is prohibited by U.S. Export Control Laws and Economic Sanctions. Violations of these Laws could result in criminal and/or civil penalties, loss of research contracts, government funding, and/or the ability to export items.

U.S. Export Control Laws apply to Items Exported or Re-exported from the U.S. Export Control Laws prohibit the unauthorized Export or Re-export of Dual-Use Items without a prior license (i) to Embargoed Countries; (ii) to Restricted Persons; and (iii) for Prohibited Purposes.

Dual-Use Items may be specifically described and identified on the CCL and assigned Export Control Classification Numbers or they may be generally classified under the catch-all category of EAR99. Items specifically identified on the CCL are restricted for purposes that correlate with named countries. For example, if regulated for national security reasons, then Exports/Re-exports of Items to all countries except Canada require a license from BIS.

Items that are classified as EAR99 are only restricted for Exports/Re-exports to Embargoed Countries, Restricted Persons, and Prohibited Purposes. Employees are prohibited from engaging in any transactions with Embargoed Countries, Restricted Persons or for Prohibited Uses without the prior written approval from Research Compliance.

All persons performing research at Allina Health may engage in research involving certain Biological Agents, Vaccines and Toxins or they may have access to such substances and Medical Products. U.S. Export Control Laws prohibit Foreign Persons from research or having access to research involving Biological Agents unless the research meets the requirements of FRE or a prior license is obtained from BIS.

These Laws also restrict Foreign Persons from Embargoed Countries from research or having access to research involving Vaccines and Toxins unless the research meets the requirements of FRE or a prior license is obtained from BIS.

To comply with applicable law, Allina Health does not allow Foreign Persons to conduct research or have access to research involving Biological Agents without being appropriately licensed in advance and having prior approval from Research Compliance. Also, Allina Health does not allow Foreign Persons from Embargoed Countries to conduct research or have access to research involving Vaccines, Toxins or Medical Products containing Toxins without being appropriately licensed and having prior approval from Research Compliance. With respect to any proposed research project or study involving Biological Agents, Vaccines, Toxins or Medical Products, Research Compliance will be responsible for determining whether the requirements of FRE have been met.

Economic Sanctions prohibit U.S. persons from transacting business of any kind with Embargoed Countries, including persons in or normally resident in Embargoed Countries, and persons on the SDN List without a prior license from OFAC. Employees are prohibited from engaging in any transactions with Embargoed Countries or persons on the SDN List without the prior written approval from Research Compliance.

Any questions or concerns can be sent to Research Compliance at researchcompliance@allina.com.

DEFINITIONS:

Biological Agents: Certain viruses, bacteria, toxins, fungi, genetic elements and genetically modified organisms and plant pathogens that are specifically described on the CCL, identified on [Exhibit I](#).

Bureau of Industry and Security (BIS): Is a bureau of the Department of Commerce responsible for implementing and enforcing the EAR.

Commerce Control List (CCL): A list of Dual Use Items controlled for Export or Re-export for reasons that correlate to lists of countries; for example, Anti-terrorism (AT), Chemical & Biological (CB), Chemical Weapons Convention (CW), Crime Control (CC), National Security (NS), Nuclear Nonproliferation (NP), Regional Stability (RS), and United Nations sanctions (UN).

Deemed Export: The release, disclosure or granting of access to export-controlled technology to a non-U.S. person who is located in the U.S.

Deemed Re-export: The release or otherwise transfer of technology subject to the EAR to a foreign person of a country other than the foreign country where the release or transfer takes place.

Dual Use Items: Items that have both commercial and military or proliferation applications.

Economic Sanctions: The Foreign Assets Control Regulations appear at 31 CFR Parts 500-598, and prohibit unauthorized transactions with embargoed countries and entities identified on the SDN List.

Embargoed Countries: Cuba, Iran, North Korea, Sudan, Syria and the Crimea region of Ukraine. This list may change from time to time.

Export: An actual shipment or transmission out of the U.S. of a product, technology or software or performance of services outside of the U.S. and Deemed Exports.

Export Administration Regulations (EAR): 15 CFR Parts 730-774 (“EAR”) as authorized by the Export Administration Act, 50 U.S.C. §§ 4601-4623, as amended, and International Emergency Economic Powers Act, 50 U.S.C. 1701-1706.

Foreign Person(s): (i) any natural person who is not a citizen of the U.S., a lawful permanent resident, or who is not a “protected person” under the Immigration and Naturalization Act (8 U.S.C. 1324b(a)(3)); (ii) any entity, corporation/business/organization/group not organized under the laws of the U.S. This applies to corporations

or partnerships not incorporated or organized to do business in the U.S., and foreign governments.

Fundamental Research Exclusion (FRE): Any basic and applied research in science and engineering, the results of which are ordinarily published and shared broadly within the scientific community. The Research must be conducted free of any publication restrictions and without any access or dissemination restrictions. (15 CFR §734.8).

Items: Products, related technology, software and services as these terms are defined in the EAR.

Laws: Laws, regulations, orders, rules and licenses.

Medical Products: Medical products, diagnostic and food testing kits specifically described on the CCL and which contain Toxins identified on [Exhibit I](#).

Office of Foreign Assets Control (OFAC): An office of the U.S. Department of Treasury responsible for administering and enforcing Economic Sanctions.

Prohibited Purpose: With knowledge that Items will be used in connection with nuclear, rocket systems, chemical or biological weapons end-uses.

Public Domain: Information that is published and generally accessible to the public.

Re-export: An actual shipment or transmission of an Item from one foreign country to another foreign country.

Restricted Persons: means any individual or entity listed on the lists maintained by the BIS at <https://www.export.gov/csl-search>.

Specially Designated Nationals (SDN) List: Administered by OFAC, <https://sanctionssearch.ofac.treas.gov/>.

Subject to the EAR: Items that are (i) Exported from or through the U.S.; (ii) foreign products containing more than 25% U.S. origin (or with respect to Exports to Embargoed Countries, 10% U.S. origin content), and (iii) certain foreign products, software or technology that integrate U.S. products, software or technology. Technology or software that arises during, or results from, fundamental research and is intended to be published without restriction is not Subject to the EAR.

U.S. Export Control Laws: Laws, regulations, orders and licenses (“Laws”) relating to the export of Items.

U.S. Person(s): (i) any individual who is granted U.S. citizenship, a lawful permanent residence (green card holder), has a status as a “protected person” under 8 U.S.C. 1324b(a)(3) which includes political asylum holder; and (ii) any entity,



corporation/business/organization/group incorporated in the United States under U.S. law, or any branch thereof, or any part of the U.S. government.

Toxins: Certain toxins identified on [Exhibit I](#).

Vaccines: Certain vaccines containing Biological Agents identified on [Exhibit I](#).

PROCEDURES: Not applicable.

FORMS: Not applicable.

REFERENCES:

Related Regulation and Laws:

Export Control Laws: EAR: 15 CFR Parts 730-774as authorized by the Export Administration Act, 50 U.S.C. §§ 4601-4623, as amended, and International Emergency Economic Powers Act, 50 U.S.C. 1701-1706 (“IEEPA”). <https://www.bis.doc.gov/index.php/regulations/export-administration-regulations-ear>;

Economic Sanctions: Trading with the Enemy Act, 50 U.S.C. App. 1 – 44 (“TWEA”); IEEPA; Executive Orders issued pursuant to TWEA and IEEPA; The Foreign Assets Control Regulations, 31 CFR Parts 500-598.

RELATED POLICIES/DOCUMENTS:

Name of Policy	Content ID	Business Unit where Originated
N/A		

POLICIES/DOCUMENTS REPLACING:

Name of Policy	Content ID	Business Unit where Originated
N/A		

Exhibit I

1. Biological Agents: Export to any country requires license, no Foreign Person involvement in research, if results will not meet FRE (be publicly available and published without restriction):

a. *Viruses*

African horse sickness virus;

African swine fever virus;

Andes virus;

Avian influenza (AI) viruses identified as having high pathogenicity (HP), as follows:

AI viruses that have an intravenous pathogenicity index (IVPI) in 6-week-old chickens greater than 1.2; or

AI viruses that cause at least 75% mortality in 4- to 8-week-old chickens infected intravenously.

a.5. Bluetongue virus;

Chapare virus;

Chikungunya virus;

Choclo virus;

Classical swine fever virus (Hog cholera virus);

Crimean-Congo hemorrhagic fever virus;

Dobrava-Belgrade virus;

Eastern equine encephalitis virus;

Ebolavirus (includes all members of the Ebolavirus genus);

Foot-and-mouth disease virus;

Goatpox virus;

Guanarito virus;

Hantaan virus;

Hendra virus (Equine morbillivirus);

Japanese encephalitis virus;

Junin virus;

Kyasanur Forest disease virus;

Laguna Negra virus;

Lassa virus;

Louping ill virus;

Lujo virus;

Lumpy skin disease virus;

Lymphocytic choriomeningitis virus;

Machupo virus;

Marburgvirus (includes all members of the Marburgvirus genus);

Monkeypox virus;

Murray Valley encephalitis virus;

Newcastle disease virus;

Nipah virus;

Omsk hemorrhagic fever virus;

Oropouche virus;

Peste-des-petits ruminants virus;

Porcine Teschovirus;
Powassan virus;
Rabies virus and all other members of the Lyssavirus genus;
Reconstructed 1918 influenza virus;
Rift Valley fever virus;
Rinderpest virus;
Rocio virus;
Sabia virus;
Seoul virus;
Severe acute respiratory syndrome-related coronavirus (SARS-related coronavirus);
Sheeppox virus;
Sin Nombre virus;
St. Louis encephalitis virus;
Suid herpesvirus 1 (Pseudorabies virus; Aujeszky's disease);
Swine vesicular disease virus;
Tick-borne encephalitis virus (Far Eastern subtype, formerly known as Russian Spring-Summer encephalitis virus);
Tick-borne encephalitis virus (Siberian subtype, formerly West Siberian virus—
Variola virus;
Venezuelan equine encephalitis virus;
Vesicular stomatitis virus;
Western equine encephalitis virus; or
Yellow fever virus.

b. Bacteria

Bacillus anthracis;
Brucella abortus;
Brucella melitensis;
Brucella suis;
Burkholderia mallei (Pseudomonas mallei);
Burkholderia pseudomallei (Pseudomonas pseudomallei);
Chlamydia psittaci (Chlamydophila psittaci);
Clostridium argentinense (formerly known as Clostridium botulinum Type G), botulinum neurotoxin producing strains;
Clostridium baratii, botulinum neurotoxin producing strains;
Clostridium botulinum;
Clostridium butyricum, botulinum neurotoxin producing strains;
Clostridium perfringens, epsilon toxin producing types;
Coxiella burnetii;
Francisella tularensis;
Mycoplasma capricolum subspecies capripneumoniae (“strain F38”);
Mycoplasma mycoides subspecies mycoides SC (small colony) (a.k.a. contagious bovine pleuropneumonia);
Rickettsia prowazekii;
Salmonella enterica subspecies enterica serovar Typhi (Salmonella typhi);
Shiga toxin producing Escherichia coli (STEC) of serogroups O26, O45, O103, O104,

O111, O121, O145, O157, and other shiga toxin producing serogroups;
Shigella dysenteriae;
Vibrio cholerae; or
Yersinia pestis.

c. Toxins

Abrin;
Aflatoxins;
Botulinum toxins;
Cholera toxin;
Clostridium perfringens alpha, beta 1, beta 2, epsilon and iota toxins;
Conotoxins;
Diacetoxyscirpenol;
HT-2 toxin; d.9. Microcystins (Cyanginosins);
Modeccin;
Ricin;
Saxitoxin;
Shiga toxins (shiga-like toxins, verotoxins, and verocytotoxins);
Staphylococcus aureus enterotoxins, hemolysin alpha toxin, and toxic shock syndrome toxin (formerly known as Staphylococcus enterotoxin F);
T-2 toxin;
Tetrodotoxin;
Viscumin (Viscum album lectin 1); or
Volkensin.

d. Fungi

Coccidioides immitis; or
Coccidioides posadasii.

e. Genetic elements and genetically modified organisms

Genetic elements that contain nucleic acid sequences associated with the pathogenicity of viruses, toxins or plant pathogens (listed above)

Genetic elements that contain nucleic acid sequences coding for any of the toxins (listed above) sub-units of toxins thereof.

Genetically modified organisms, as follows:

Genetically modified organisms that contain nucleic acid sequences associated with the pathogenicity of microorganisms of viruses and bacteria or plant pathogens (listed herein);

Genetically modified organisms that contain nucleic acid sequences coding for any of the "toxins" (listed above) or sub-units of toxins thereof.

f. Plant Pathogens

Bacteria (Plant)

Xanthomonas albilineans;
Xanthomonas axonopodis pv. Citri (Xanthomonas campestris pv. citri A) (Xanthomonas campestris pv. citri);

Xanthomonas oryzae;
Clavibacter michiganensis subspecies sepedonicus (syn. Corynebacterium michiganensis subspecies sepedonicum or Corynebacterium sepedonicum);
Ralstonia solanacearum, race 3, biovar 2;
Raythayibactor toxicus

g. Fungi (Plant)

Colletotrichum kahawae (Colletotrichum coffeanum var. virulans);
Cochliobolus miyabeanus (Helminthosporium oryzae);
Microcyclus ulei (syn. Dothidella ulei);
Puccinia graminis ssp. graminis var. graminis / Puccinia graminis ssp. graminis var. stakmanii (Puccinia graminis [syn. Puccinia graminis f. sp. tritici]);
Puccinia striiformis (syn. Puccinia glumarum);
Magnaporthe oryzae (Pyricularia oryzae);
Peronosclerospora philippinensis (Peronosclerospora sacchari);
Sclerophthora rayssiae var. zeae;
Synchytrium endobioticum;
Tilletia indica;
Thecaphora solani;
Phoma glycinicola (formerly Pyrenochaeta glycines)

h. Viruses (Plant)

Andean potato latent virus (Potato Andean latent tymovirus);
Potato spindle tuber viroid

2. Toxins: Exports to certain CB, col 3 countries are prohibited without a license: Afghanistan, Armenia, Azerbaijan, Bahrain, Belarus, Burma, China, Cuba, Egypt, Georgia, Iran, Iraq, Israel, Jordan, Kazakstan, Kuwait, Kyrgyzstan, Lebanon, Libya, Macau, Moldova, Mongolia, North Korea, Oman, Pakistan, Qatar, Russia, Saudi Arabia, Sudan, Syria, Taiwan, Tajikistan, Turkmenistan, UAE, Crimea Region of the Ukraine, Uzbekistan, Vietnam, Yemen. Foreign Persons from these countries cannot be involved in research, if FRE requirements not met (i.e., results will not be publicly available and published without restriction).

Abrin;
Aflatoxins;
Cholera toxin;
Clostridium perfringens alpha, beta 1, beta 2, epsilon and iota toxins;
Diacetoxyscirpenol;
HT-2 toxin; d.9. Microcystins (Cyanginosins);
Modeccin;
Shiga toxins (shiga-like toxins, verotoxins, and verocytotoxins);
Staphylococcus aureus enterotoxins, hemolysin alpha toxin, and toxic shock syndrome toxin (formerly known as Staphylococcus enterotoxin F);
T-2 toxin;
Tetrodotoxin;

Viscumin (*Viscum album* lectin 1); or
Volkensin.

3. Vaccines and Medical Products (medical products, diagnostic and food testing kits):
Exports to Cuba, Iran, North Korea, Sudan, Syria, Crimea region of Ukraine requires license. Foreign nationals of those countries cannot be involved in research, if results will not be publicly available and published without restriction).

Vaccines against viruses, toxins and bacteria (listed above in 1.a – c);
Immunotoxins containing toxins (listed above in 1.c);
Medical products containing botulinum toxins and conotoxins;
Diagnostic and food testing kits containing toxins (listed above in 1.c).

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