

Risks in Healthcare Research: Applying Export Controls to Medical Centers

## Resource Guide

## OFAC

If you are a 501(c)(3), you may be able to qualify as an NGO. See Guidance for NGOs providing humanitarian assistance: <a href="https://home.treasury.gov/system/files/126/ngo">https://home.treasury.gov/system/files/126/ngo</a> humanitarian.pdf

Fact Sheet: Provision of Humanitarian Assistance and Trade to Combat COVID-19 (rev 2021): https://home.treasury.gov/system/files/126/covid19\_factsheet\_20200416.pdf

## Cuba

General License §515.547 Certain transactions related to medical research and Cuban-origin pharmaceuticals; research samples. <u>https://www.ecfr.gov/current/title-31/subtitle-</u> B/chapter-V/part-515/subpart-E/section-515.547

Note: This does <u>not</u> authorize travel incident to the research. Be sure to check §515.564 (U.S. to Cuba for research) and/or §515.571 (Cuba travel to the U.S.)

The import of Cuba-origin pharmaceuticals is only generally authorized if part of the process to obtain FDA approval. Import of research samples otherwise requires a Specific License.

General License §515.575 Humanitarian projects. These projects include "medical and health-related projects" https://www.ecfr.gov/current/title-31/subtitle-B/chapter-V/part-515/subpart-E/section-515.575

General License §515.589 Authorization of emergency medical services. <u>https://www.ecfr.gov/current/title-31/subtitle-</u> B/chapter-V/part-515/subpart-E/section-515.589

### North Korea

General License §510.509 Emergency medical services. https://www.ecfr.gov/current/title-31/subtitle-B/chapter-V/part-510/subpart-E/section-510.509

General License §510.512 Certain services in support of nongovernmental organizations' activities. Allows NGOs to provide health-related services and distribute medicine, support non-commercial development projects intended to prevent infectious disease and/or promote maternal & child health. <u>https://www.ecfr.gov/current/title-31/subtitle-B/chapter-</u> <u>V/part-510/subpart-E/section-510.512</u>

#### Iran

General License §560.530 Commercial sales, exportation, and reexportation of agricultural commodities, medicine, medical devices, and certain related software and services. https://www.ecfr.gov/current/title-31/subtitle-B/chapter-V/part-560/subpart-E/section-560.530

> List of medical devices requiring specific authorization (not eligible for the General License): <u>https://home.treasury.gov/system/files/126/iran\_gl\_m</u> ed\_supplies.pdf

Specific License §560.545 Democracy and human rights in Iran and academic and cultural exchange programs. Requires a Specific License to provide donated medical services. <u>https://www.ecfr.gov/current/title-31/subtitle-B/chapter-V/part-560/subpart-E/section-560.545</u>

Trade Sanctions Reform and Export Enhancement Act of 2000 (TSRA) Program: <u>https://home.treasury.gov/policy-</u> issues/financial-sanctions/ofac-license-application-page/tradesanctions-reform-and-export-enhancement-act-of-2000-tsraprogram

#### Syria

General License §569.508 Emergency medical services. https://www.ecfr.gov/current/title-31/subtitle-B/chapter-V/part-569/subpart-E/section-569.508

General License §542.516 Certain services in support of nongovernmental organizations' activities authorized. Permits NGOs to provide medical services and distribute medicine. <u>https://www.ecfr.gov/current/title-31/subtitle-B/chapter-V/part-542/subpart-E/section-542.516</u>

#### Ukraine

Crimea General License 4 Authorizing the Exportation or Reexportation of Agricultural Commodities, Medicine, Medical Supplies, and Replacement Parts. <a href="https://home.treasury.gov/system/files/126/ukraine\_gl4.pdf">https://home.treasury.gov/system/files/126/ukraine\_gl4.pdf</a>

Authorized medical supplies: https://home.treasury.gov/system/files/126/med\_supplies\_ukr.pdf

General License §589.508 Authorization of emergency medical services. <u>https://www.ecfr.gov/current/title-31/subtitle-B/chapter-V/part-589/subpart-E/section-589.508</u>

Covered Regions General License 18 Authorizing the Exportation or Reexportation of Agricultural Commodities, Medicine, Medical Devices, Replacement Parts and Components, or Software Updates to Certain Regions of Ukraine and Transactions Related to the Coronavirus Disease 2019 (COVID-19) Pandemic. <u>https://home.treasury.gov/system/files/126/ukraine\_gl18.pdf</u>

Covered Regions General License 23 Certain Transactions in Support of Nongovernmental Organizations' Activities. Permits NGOs to provide health services and distribute medicine. <u>https://home.treasury.gov/system/files/126/ukraine\_gl23.pdf</u>

#### Russia

General License 6A Transactions Related to the Exportation or Reexportation of Agricultural Commodities, Medicine, Medical Devices, Replacement Parts and Components, or Software Updates, the Coronavirus Disease 2019 (COVID-19) Pandemic, or Clinical Trials. https://home.treasury.gov/system/files/126/russia\_gl6a.pdf

General License 7 Authorizing Overflight Payments, Emergency Landings, and Air Ambulance Services. Permits air ambulance services, medical services, and/or medical evacuation to persons in Russia. <u>https://home.treasury.gov/system/files/126/russia\_gl7.pdf</u>

General License 27 Authorizing Certain Transactions in Support of Nongovernmental Organizations' Activities. Permits NGOs to provide health services and distribute medicine. <u>https://home.treasury.gov/system/files/126/russia\_gl27.pdf</u>

#### EAR

Supplement No. 3 to part 774(a) – Statement of Understanding – medical equipment. <u>https://www.ecfr.gov/current/title-15/subtitle-B/chapter-VII/subchapter-C/part-774/appendix-Supplement%20No.%203%20to%20Part%20774</u>

#### BIS list of EAR99 medical devices.

https://www.bis.doc.gov/index.php/documents/product-guidance/711-bis-listof-ear99-medical-devices

#### BIS landing page on chemical & biological controls.

https://www.bis.doc.gov/index.php/policy-guidance/product-guidance/chemicaland-biological-controls

BIS COVID FAQs: <u>https://www.bis.doc.gov/index.php/documents/pdfs/2532-</u> severe-acute-respiratory-syndrome-coronavirus-2-sars-cov-2-fag/file

# CCL Category 1 (Special Materials and Related Equipment, Chemicals, "Microorganisms," and "Toxins").

https://www.bis.doc.gov/index.php/documents/regulations-docs/2332-category-1-materials-chemicals-microorganisms-and-toxins-4/file

#### ITAR

USML Category XIV – Toxicological Agents, Including Chemical Agents, Biological Agents, and Associated Equipment. <u>https://www.ecfr.gov/current/title-22/chapter-</u> I/subchapter-M/part-121

#### **IMPORTS**

Even though most institutions use their Environmental Health & Safety programs for imports and/or domestic transfers of biological materials, export control officers may play a role in those processes. U.S. Customs & Border Patrol (CBP) enforces other agencies' regulations; permits may be required. See https://www.cbp.gov/trade/basic-importexport/what-you-need-know-importingbiological-materials-united-states (with links to other agencies' permitting programs).