# VUMC Export Compliance

## Export-Controlled & Restricted Vaccines, Immunotoxins, Medical Products, & Diagnostic and Food Testing Kits

**Controlled items:**

- Vaccines containing, or designed for use against, items controlled by under the following lists:
  - Viruses
  - Bacteria
  - Toxins
- Immunotoxins containing toxins controlled by the Toxin list above;
- Medical products that contain any of the following:
  - Toxins controlled by the Toxin list above; *or*
  - Genetically modified organisms or genetic elements controlled by the Genetic Element list;
- Medical products that contain any of the following:
  - Botulinum neurotoxins;
  - Conotoxins
- Diagnostic and food testing kits containing toxins controlled by the Toxin list above.

Definitions:

1. 'Vaccine' is defined as a medicinal (or veterinary) product in a pharmaceutical formulation, approved by the U.S. Food and Drug Administration or the U.S. Department of Agriculture to be marketed as a medical (or veterinary) product or for use in clinical trials, that is intended to stimulate a protective immunological response in humans or animals in order to prevent disease in those to whom or to which it is administered.
2. 'Immunotoxins' are monoclonal antibodies linked to a toxin with the intention of destroying a specific target cell while leaving adjacent cells intact.
3. 'Medical products' are:
   a. Pharmaceutical formulations designed for testing and human (or veterinary) administration in the treatment of medical conditions,
   b. prepackaged for distribution as clinical or medical products, and
   c. approved by the U.S. Food and Drug Administration either to be marketed as clinical or medical products or for use as an “Investigational New Drug” (IND) (see 21 CFR part 312).
4. 'Diagnostic and food testing kits' are specifically developed, packaged and marketed for diagnostic or public health purposes.

Special Notes:

1. The export of a “medical product” that is an “Investigational New Drug” (IND), as defined in 21 CFR 312.3, is subject to certain U.S. Food and Drug Administration (FDA) requirements that are independent of the export requirements specified in the U.S. Export Control Regulations (EAR, ITAR, OFAC, etc.) These FDA requirements are described in 21 CFR 312.110 and must be satisfied in addition to any requirements specified in the EAR.
2. Also see 21 CFR 314.410 for FDA requirements concerning exports of new drugs and new drug substances.