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

Controlled items:

- Vaccines containing, or designed for use against, items controlled by under the following lists:
  - Viruses
  - Bacteria
  - Fungi
- Immunotoxins containing toxins controlled by the Toxin list;
- Medical products that contain any of the following:
  - Toxins controlled by the Toxin list above (including Botulinum toxins or Conotoxins); or
  - Genetically modified organisms or genetic elements controlled by the Genetic Element list;
- 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.

3. The items above on this list are controlled for Anti-Terrorism and Chemical & Biological Weaponry purposes:
   a. This level of control requires a USG-approved export license for the following 37 destinations:
      1. Afghanistan
      2. Armenia
      3. Azerbaijan
      4. Bahrain
      5. Belarus
      6. Burma (Myanmar)
      7. China
      8. Cuba
      9. Egypt
      10. Georgia
      11. Iran
      12. Iraq
      13. Israel
      14. Jordan
      15. Kazakhstan
      16. North Korea
      17. Kuwait
      18. Kyrgyzstan
      19. Lebanon
      20. Libya
      21. Macau
      22. Moldova
      23. Mongolia
      24. Oman
      25. Pakistan
      26. Qatar
      27. Russia
      28. Saudi Arabia
      29. Syria
      30. Taiwan
      31. Tajikistan
      32. Turkmenistan
      33. United Arab Emirates
      34. Uzbekistan
      35. Venezuela
      36. Vietnam
      37. Yemen