

TRANSPORTING CLINICAL RESEARCH SAMPLES FROM OFFSITE LOCATIONS: MATERIALS OF TRADE EXCEPTIONS

This guidance document covers the transport of clinical samples from offsite locations to the main campus of Vanderbilt University Medical Center in a private vehicle. Transport of hazardous materials over the open roadways is regulated by the U.S. Department of Transportation (DOT) as described in the Hazardous Materials Regulations (49 CFR 173-180). There is a provision in the regulations for transport of some classes of hazardous materials in support of your job; these materials are called Materials of Trade (49 CFR 171.8).

Clinical samples and materials that can be transported as a Material of Trade

Most clinical samples will fall under the allowed definition in 49 CFR 173.6 (a) (4) which allows “human or animal samples (including, but not limited to, secreta, excreta, blood and its components, tissue and tissue fluids, and body parts) being transported for research, diagnosis, investigational activities, or disease treatment or prevention, or is a biological product or regulated medical waste”. Small sharps containers used to collect any biohazardous sharps are allowed as regulated medical waste.

Any clinical sample or medical waste known to contain a Category A Infectious Substance, defined as infectious substance in a form capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans [49 CFR 173.134 (a) (1) (i)], cannot be transported as a Material of Trade. As this refers to high risk infectious agents like Ebola, this restriction is not expected to be triggered often.

Packaging requirements for biological hazardous materials transported as a Material of Trade

All materials must be transported in combination packaging, consisting of an inner packaging that holds the sample, such as a blood tube, and an outer packaging, such as a cardboard box or plastic cooler. The outer packaging must be made of sturdy material and be securely closed for transport. The outer packaging should be marked with the common name of what it contains. There are specific guidelines depending on the form of the materials. Below is a summary of the requirements found in 49 CFR 173.6 (a) (4) (i).

Liquids/Solids

The inner packaging must be leakproof/siftproof. If it is a liquid sample, the outer packaging must contain sufficient absorbent material to absorb the entire contents of the inner packaging. Each inner packaging cannot hold more than 0.5L/0.5 kg of sample and each outer packaging cannot hold more than 4L/4kg of material.

Sharps

The inner packaging (sharps container) must be constructed of a rigid material resistant to punctures and securely closed to prevent leaks or punctures, and the outer packaging must be securely closed to prevent leaks or punctures. Each inner packaging can hold no more than 4kg and the outer packaging no more than 16kg.

Securing the packages in your vehicle

All packages must be secured against shifting, including relative motion between packages, within the vehicle on which it is being transported [49 CFR 173.6 (a) (4)]. It is a judgement call to determine where is the safest place in your vehicle to place a Materials of Trade package. We suggest on the floor of the passenger side back seat secured by the front seat pushed back, buckled into the back seat, or in the trunk secured in place with cords or cargo netting.

Training

There is no formal training required to transport Materials of Trade. However, the regulations state that the driver of the vehicle must be informed about the Materials of Trade onboard and the requirements of the regulations [49 CFR 171.8 (c) (4)]. **Anyone transporting Materials of Trade should read this guidance document and keep a copy of this document with every Materials of Trade package for reference.**

This document outlines the minimum USDOT requirements for transporting clinical research samples in a private vehicle. If you have additional questions beyond the scope of this document, please contact Robin Trundy or Richard DiTullio at 322-2057 for assistance.