

University of Nebraska Medical Center  
 Biosafety Policies and Procedures

<b>TITLE:</b>	<b>Federal Permits to Ship or Receive Human Pathogens Including Select Agents</b> [UNMC-IBC32]
<b>OVERVIEW:</b>	Federal permits are required for the interstate transport and/or importation of etiological agents, hosts, and vectors of human disease within or into the US.
<b>APPLIES TO:</b>	All individuals receiving a human pathogen from an international source (importation) and receiving a human/animal (zoonotic) pathogen from a domestic source. Shipment to a domestic source requires the recipient to have the proper permit. Shipment to an international source (export) requires the laws of the country where the sample is shipped to be followed.
<b>DEFINITION(S):</b>	<p><b>CDC Etiologic Agent Import Permit (EAIPP)</b>- Office of Public Health and Safety “Permit to Import or Transfer Etiological Agents or Vectors of Human Disease (CDC 0.728) “is issued under federal guidelines (42CFR Part 71.54) which is required to import and distribute after importation any etiological agent, or any arthropod or other animal host or vector of human disease, or any exotic living arthropods or animal capable of being a host or vector of human disease.</p> <p><b>VS16 permit</b> - U.S. Department of Agriculture/ Animal and Plant Health Inspection Service (USDA/APHIS) permit to “Import or transport controlled material or organisms or vectors required to import or transfer animal pathogens capable of causing disease in humans i.e., zoonotic pathogen.” No organisms or vectors shall be imported into the US or transported from one State or Territory to another State or Territory without a permit issued by the (USDA) Secretary (9CFR Part 122.2, APHIS, Organisms and Vectors).</p> <p><b>Select Agents</b> - specific organisms and toxins that have been determined to pose a severe threat to both human , animal and plant health, require a Certificate of Registration for possession as regulated by the USDA and the CDC.</p>
<b>PROCEDURES:</b>	An application for “Permit to Import or Transport Etiological Agents, Hosts, or Vectors of Human Disease (CDC Form 0.753) and/or an application for permit to “Import or Transport Controlled Material or Organisms or Vectors (VS Form 16-3) must be applied prior to the transfer process.

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	<p>Application instructions can be located at the following web pages:            VS Form 16-3  <a href="http://www.aphis.usda.gov/animal_health/permits/downloads/vs16-3inst.pdf">http://www.aphis.usda.gov/animal_health/permits/downloads/vs16-3inst.pdf</a></p> <p>CDC 0.753  <a href="http://www.cdc.gov/od/ohs/biosfty/impptper.htm">http://www.cdc.gov/od/ohs/biosfty/impptper.htm</a></p> <p>The EAIPP permit is required for the importation of human pathogens while the USDA permit is required for the transfer (whether domestic or import) of zoonotic pathogens. Examples are indicated in Appendix 1.</p> <p>Importation permits (whether PHS or USDA) are issued on a onetime shipment basis while the USDA permit for domestic transfers may be used for multiple shipments from multiple locations during a 12 month period of time.</p> <p>The interstate shipment of an animal pathogen (as described by the USDA) requires that the recipient has a valid USDA permit. Prior to shipment, the shipper is responsible to obtain from the recipient a copy of their valid permit with the agent listed as authorized for transfer.</p>
<b>RECORD KEEPING:</b>	Copies of all permits must be kept on file with the individual shipping or receiving the pathogen for a period of at least 3 years.
<b>OTHER INFORMATION:</b>	<p>The Biosafety Officer can be contacted for information pertaining to the application for federal permits.</p> <p>Facilities shipping or receiving select agent or toxin must be certified by the US DHHS to have these agents in their possession. The Biosafety Officer, as the Responsible Official for the Select Agent Program on campus, must be contacted prior to the transfer of any select agent or toxin.</p>
<b>REFERENCES:</b>	
<b>STATUS:</b>	<p>Drafted:                      March 24, 2005            Approved:                  April 8, 2005            Revised:                     May 11, 2012</p>

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Example of pathogens that require a USDA permit for shipment.+

**A. UN2814 Infectious Substances, affecting humans (Category A) in culture**

\**Bacillus anthracis*  
\**Brucella abortus*  
\**Brucella suis*  
\**Brucella melitensis*  
\**Burkholderia mallei*  
\**Burkholderia pseudomallei*  
*Chlamydia psittaci*  
\**Clostridium botulinum* \**Coccidioides immitis*  
\**Coxiella burnetii*  
\*Eastern equine encephalitis virus  
\**Francisella tularensis*  
\*Avian influenza virus  
West Nile virus  
*Mycobacterium bovis* ??should be *M tuberculosis*??  
Rabies virus  
\*Rift Valley fever virus  
\*Venezuelan equine encephalitis virus

**B. UN2814 Infectious Substances, affecting humans (Category A) in culture and specimens expected to contain the pathogen**

\*Hendra virus  
Hantaan virus  
Hantavirus (causing hemorrhagic fever with renal syndrome)  
Monkeypox virus  
\*Nipah virus

**C. Category B in culture**

*Cryptosporidium parvum*  
*Salmonella* species  
Influenza A viruses (H3)  
*Mycobacterium avium/ intracellulare*

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+These are examples only. Contact APHIS for a complete listing of those pathogens requiring a USDA permit.

\*Select agents requiring special certification requirements for possession. Contact the Biosafety Officer for details.