Permit to Import Infectious Biological Agents, Infectious Substances, and Vectors

Your Facility will be subject to inspection as some time in the future to confirm that the importer’s biosafety measures are commensurate with the hazard posed by the items to be imported and the level of risk given its intended use.

In accordance with 42 CFR Section 71.54 of the Public Health Service Foreign Quarantine Regulators, cited on the bottom of this permit, permission is granted the permittee to import into any port under control of the United States, or to receive by transfer within the United States, the material described in item 1 below.

PHS PERMIT NO. 2016-02-047

1. DESCRIPTION OF MATERIAL

HUMAN BLOOD/BLOOD PRODUCTS, BODY FLUIDS, TISSUES/ORGANS, AND ISOLATES THAT MAY CONTAIN OR ARE BORRELIA SPECIES, ACTINOMYCES SPECIES, LEPTOSPIRA SPECIES, MYCOBACTERIUM SPECIES, NOCARDIA SPECIES, CANDIDA SPECIES, CRYPTOCOCCUS SPECIES, BLASTOMYCES SPECIES, HISTOPLASMA SPECIES, ADENOVIRUS SPECIES, CYTOMEGALOVIRUS, EPSTEIN-BARR VIRUS, HEPATITIS A-E VIRUS, HERPES SIMPLEX VIRUS, HUMAN IMMUNODEFICIENCY VIRUS (TYPE 1-2), HUMAN T-CELL LYMPHOTROPIC VIRUS (TYPE 1-2), INFLUENZA A VIRUS (H3N2), RESPIRATORY SYNCYTIAL VIRUS, VARICELLA ZOSTER VIRUS, ENTAMOEBA SPECIES, TOXOPLASMA SPECIES, ACANTHAMOEBA SPECIES, BABESIA SPECIES, NAEGLELA FOWLER, STRONGYLOIDES SPECIES, AND BALMUTHIA MADRILARIS.

AS THE PERMITTEE, YOUR FACILITY WILL BE SUBJECT TO INSPECTION AT SOME TIME IN THE FUTURE TO CONFIRM THAT THE IMPORTER’S BIOSAFETY MEASURES ARE COMMENSURATE WITH THE HAZARD POSED BY THE ITEMS TO BE IMPORTED AND THE LEVEL OF RISK GIVEN ITS INTENDED USE.

2. PERMITTEE (NAME, ORGANIZATION, ADDRESS AND CONTACT INFORMATION)

ROBIN PATEL
MAYO MEDICAL LABORATORIES
3050 SUPERIOR DRIVE N.W.
ROCHESTER, MN 55901

TEL: 507-266-5700
FAX: 507-284-1790

3. SOURCE OF MATERIAL (NAME, ORGANIZATION, ADDRESS, COUNTRY)

WORLDWIDE

4. TYPE OF PERMIT AND INSTRUCTIONS FOR USE

☑ Single Importation into the U.S. ☐ Single Transfer Within the U.S.
☑ Multiple Importation into the U.S. ☐ Multiple Transfer Within the U.S.

A. Record of each importation shall be maintained on permanent file by permittee.
B. Enclosed label(s) must be forwarded to the shipper(s).
C. One label shall be affixed to shipping container. Enclosed labels may be photocopied.

5. CONDITIONS OF ISSUANCE ITEMS APPLICABLE WHEN CHECKED

☐ A. Subsequent distribution, within the U.S., of the material described in this permit is prohibited without prior authorization by the Public Health Service.
☐ B. All material is for laboratory use only - Not for use in the production of biologics for humans or animals.
☐ C. All material is free of tissues, serum and plasma of domestic and wild ruminants, swine and equines.
☐ D. Additional Requirements:
   □ IATA Packaged to preclude escape.
   □ USDA permit may be required (Telephone: 301-851-3300).
☐ E. Work with the agent(s) described shall be restricted to areas and conditions meeting requirements in the CDC/NIH publication “Biosafety in Microbiological and Biomedical Laboratories.”
☐ F. Packaging must conform to 49 CFR Sections 171-180.

6. Signature of Issuing officer

Daniel Sosin, MD, MPH, FACP Acting Director, Division of Select Agents and Toxins
A person may not import into the United States any infectious biological agent, infectious substance, or vector unless:

- It is accompanied by a permit issued by the Centers for Disease Control and Prevention (CDC).

The possession of a permit issued by the CDC does not satisfy permitting requirements placed on materials by the U.S. Department of Agriculture that may pose hazards to agriculture or agricultural production in addition to hazards to human health.

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A person may not import into the United States any infectious biological agent, infectious substance, or vector unless: It is accompanied by a permit issued by the Centers for Disease Control and Prevention (CDC). The possession of a permit issued by the CDC does not satisfy permitting requirements placed on materials by the U.S. Department of Agriculture that may pose hazards to agriculture or agricultural production in addition to hazards to human health.