

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE**

Centers for Disease Control and Prevention
Division of Regulatory Science and Compliance
1600 Clifton Road NE, Mailstop H21-7
Atlanta, GA 30329
Telephone: 404-718-2077; 404-488-7100 (after hours) Email: importpermit@cdc.gov



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

In accordance with 42 CFR Section 71.54 of the Public Health Service Foreign Quarantine Regulations, 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. : 20250416-1277A

ISSUED DATE: 04/21/2025

EXPIRATION DATE: 04/21/2026

1. DESCRIPTION OF MATERIAL

BLOOD/BLOOD PRODUCTS, TISSUES, OTHER BODILY FLUIDS FROM HUMANS THAT MAY CONTAIN: HEPATITIS B VIRUS; LENTIVIRUS (HUMAN IMMUNODEFICIENCY VIRUS 1, 2); MYCOBACTERIUM TUBERCULOSIS

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

ALEX FEDERLINE (202) 815-0820

BIOMEDICAL RESEARCH INSTITUTE
9410 KEY WEST AVENUE
ROCKVILLE MD 20850

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

WORLDWIDE

4. TYPE OF PERMIT AND INSTRUCTIONS
FOR USE

MULTIPLE IMPORTATIONS

A. RECORD OF EACH IMPORTATION SHALL BE MAINTAINED ON PERMANENT FILE BY PERMITTEE.

B. USDA/APHIS MAY REQUIRE ADDITIONAL PERMITS FOR MATERIALS FROM ANIMALS, MATERIALS EXPOSED TO ANIMAL PRODUCTS/BYPRODUCTS, AND AGENTS THAT ARE INFECTIOUS TO ANIMALS OR PLANTS. U.S. FISH AND WILDLIFE SERVICE MAY REQUIRE ADDITIONAL PERMITS FOR MATERIALS FROM ENDANGERED ANIMALS.

5. CONDITIONS OF ISSUANCE ITEMS APPLICABLE
WHEN CHECKED

PACKAGING MUST CONFORM TO 49 CFR SECTIONS 171-180.

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.

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

THE CONDITIONS FOR IMPORTATION AND CONTINUED POSSESSION LISTED ON THE CDC PERMIT REMAIN IN EFFECT UNTIL THE IMPORTER IS NO LONGER IN POSSESSION OF THE IMPORTED MATERIAL.

ALL MATERIAL IS FOR LABORATORY USE ONLY - NOT FOR USE IN THE PRODUCTION OF BIOLOGICS FOR HUMANS OR ANIMALS.

THE SUBSEQUENT DISTRIBUTION OF MYCOBACTERIUM TUBERCULOSIS WILL REQUIRE AN ADDITIONAL SEPARATE PERMIT.

6. SIGNATURE OF ISSUING OFFICER

A handwritten signature in cursive script, appearing to read "S. Jorgensen".

SHELLEY JORGENSEN
DIRECTOR, DIVISION OF REGULATORY SCIENCE AND COMPLIANCE
CENTERS FOR DISEASE CONTROL AND PREVENTION
DEPARTMENT OF HEALTH AND HUMAN SERVICES