

Import Regulations for Infectious Biological Agents,
Infectious Substances, and Vectors (42 CFR 71.54)
(OMB Control No. 0920-0199)
Non-Substantive Change Request

Centers for Disease Control and Prevention
Center for Preparedness and Response
Division of Select Agents and Toxins

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Justification

Section 361 of the Public Health Service Act (42 U.S.C. 264), as amended, authorizes that the Secretary of Health and Human Services (HHS) make and enforce such regulations as are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession. Part 71 of Title 42, Code of Federal Regulations (Foreign Quarantine) sets forth provisions to prevent the introduction, transmission, and spread of communicable disease from foreign countries into the United States. Subpart F – Importations - contains provisions for the importation of infectious biological agents, infectious substances, and vectors (42 CFR 71.54); requiring persons that import these materials to obtain a permit issued by the CDC. The Centers for Disease Control and Prevention's Import Permit Program (IPP) regulates the importation of infectious biological agents, infectious substances, and vectors (which includes human remains and body parts) of human disease into the United States. Prior to issuing an import permit, IPP reviews all applications to ensure that entities have appropriate safety measures in place for working safely with these imported materials. CDC plans to introduce this new form as a result of the Importation of Human Remains (42 CFR 71.55) Notice of Proposed Rulemaking that was published in the Federal Register on November 25, 2019, Vol. 84, No. 227, Pages 64808-64819.

This information will assist with meeting the goals of the Section 361 of the Public Health Service (PHS) Act (42 U.S.C. 264) and prevents the introduction, transmission, or spread of

communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession.

The Application for Permit to Import Infectious Human Remains into the United States (**Attachment B** – Application Permit For Importation of Human Remains) is used by facilities that will bury/cremate the imported cadaver and educational facilities to request a permit for the importation and subsequent transfers throughout the U.S. of human remains or body parts that contains biological agents, infectious substances, or vectors of human disease. This form will request applicant and sender contact information; facility processing human remains; cause of death; biosafety and containment information; and final destination(s) of imported infectious human remains.

The CDC/IPP will review the application for permits to ensure that the imported human remains have appropriate biosafety measures in place to protect the public from exposure to blood and other body fluids during transportation, inspection, and/or storage of human remains that may be infected with SARS-CoV-2.

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Applicants Requesting to Import Infectious Human Remains into the United States	Application for Permit to Import Infectious Human Remains into the United States	100	1	20/60	33.3
Total					33.3

Total estimated cost to respondents is \$1237.39

Type of Respondent	No. of Respondents	No. Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours	Hourly Wage Rates	Total Respondent Costs
Applicants	100	1	30/60	33.3	38.24	\$1273.39
Total				33.3		\$1273.39