Supporting Statement

Import Permit Applications (42 CFR 71.54)(OMB Control No. 0920-0199)

Revision

Centers for Disease Control and Prevention

Office of Public Health Preparedness and Response

Division of Select Agents and Toxins

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- The goal of the study is to support 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 intended use of the study is to fulfill the requirements promulgated by Health and Human Services under 42 CFR 71.54.
- The method used to collect data/information is an electronic data collection system that uses electronic forms, which are available on the Centers for Disease Control and Prevention's Import Permit website at http://www.cdc.gov/od/eaipp/ in a pdf-fillable format for electronic submission.
- The subpopulation to be studied are those academic institutions and biomedical centers, commercial manufacturing facilities, federal, state, and local laboratories, including clinical and diagnostic laboratories, research facilities, exhibition facilities, and educational facilities to request a permit for the importation, and any subsequent distribution after importation, of biological agents, infectious substances, or vectors of human disease.
- This collection of information does not employ statistical methods. The data collection is mandated by 42 CFR 71.54.

A. Justification

This request reflects a new request form for the "Application for Permit to Import Infectious Human Remains into the United States" to accompany the Application for Permit to Import Biological Agents, Infectious Substances and Vectors of Human Disease into the United States form, the Application for Permit to Import or Transport Live Bats form that were approved by the Office of Management and Budget (OMB)'s until April 30, 2021 (OMB Control No. 0920-0199). CDC plans to introduce this new data collection 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 (Attachment A – Notice of Proposed Rulemaking).

The outbreak caused by a novel coronavirus (SARS-CoV-2) has resulted in requests to the Centers for Disease Control and Prevention (CDC)/Import Permit Program (IPP) to import cadavers into the United States infected with SARS-CoV-2. All human remains must be shipped in a leakproof container with an accompanying death certificate stating the cause of death. It is the goal of CDC/IPP 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. As such, CDC/IPP is taking proactive preparedness precautions and re-quires emergency expedited review and clearance approval to allow for immediate information collection regarding the importation of human remains that is infected with SARS-CoV-2 for burial. The CDC/IPP will review the application for permits to ensure that the imported hu-man 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 re-mains that may be infected with SARS-CoV-2.

1. Circumstances Making the Collection of Information Necessary

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 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 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.

2. Purpose and Use of Information Collection

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 Biological Agents and Vectors of Human Disease into the United States*** is used by laboratory facilities:, such as those operated by academic institutions and biomedical centers; commercial manufacturing facilities; federal, state, and local laboratories, including clinical and diagnostic laboratories; research facilities; exhibition facilities and educational facilities to request a permit for the importation, and any subsequent distribution after importation, of biological agents, infectious substances, or vectors of human disease. This form requests applicant and sender contact information; description of material for importation; facility isolation, storage location and containment information; and personnel qualifications, responsibilities and contact information.

The ***Application for Permit to Import Biological Agents and Vectors of Human Disease into the United States*** is used to verify that the recipient for subsequent transfers has implemented biosafety measures commensurate with the hazard posed by the infectious biological agent, infectious substance, and/or vector to be imported, and the level of risk given its intended use.

The ***Application for Permit to Import or Transfer Live Bats*** is used by laboratory facilities such as those operated by government agencies; universities; research institutions; and for

educational, exhibition or scientific purposes to request a permit for the importation, and any subsequent distribution after importation of live bats. This form requests the applicant and sender contact information; a description and intended use of bats to be imported; and facility isolation, containment information and personal protective measures.
The ***Application for Permit to Import or Transfer Live Bats – Guidance Document*** will be added to provide explicit instructions to assist with the completion of this form.

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.

3. Use of Improved Technology and Burden Reduction

The electronic forms are available at the CDC's Import Permit website (http://www.cdc.gov/od/eaipp/importApplication) in pdf and pdf-fillable formats. Applications may be emailed, mailed or sent by fax. Using the pdf-fillable form, the applicant has the ability to save the document to the applicant's local drive, complete the form, and then mail or fax the application to CDC. The use of electronic forms will facilitate a reduction in burden for those applicants submitting more than one form to CDC.

CDC is also committed to a web-based system that will allow the regulated community to conduct transactions electronically. By providing the regulated community a single web portal, CDC will be able to interact efficiently, effectively, while reducing the burden on the public. This environment will provide for the electronic exchange of information.

4. Efforts to Identify Duplication and Use of Similar Information

42 CFR 71.54 specifies that the importation permit is granted by CDC. No other component of HHS is involved in these procedures. The only way to obtain the necessary information is from the applicant.

5. Impact on Small Businesses or Other Small Entities

Collection of information may involve some small businesses or other small entities, but the burden has been limited to providing minimal information on forms, verifying information by telephone, and mailing information to the appropriate parties. CDC has made every effort to ensure that the information collection is the minimal amount necessary to meet the requirements of the law and places a minimal burden on all parties involved.

6. Consequences of Collecting the Information Less Frequently

As required by 42 CFR 71.54, applicants complete an application at least annually to ensure that entities have appropriate safety measures in place for working safely for infectious biological agents, infectious substances, and vectors that they plan to import into the United States. There are legal obstacles to reducing the burden by collecting this information less frequently. The purpose of this information collection is to meet mandated regulatory requirements. If this information were collected less frequently, it would not be possible for CDC to carry out its commitments to protect the public health as mandated by these regulations.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the regulation in 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A **"60 Day Federal Register Notice"** was published in the Federal Register on September 26, 2017, Vol. 82, No. 185, Pages 44795-44796. CDC received three comments to the docket. One comment from a frequent commenter was outside the scope of the docket. The other two commenters suggested that CDC develop a "renewable" form to reduce the burden on businesses. CDC has published a pdf-fillable form so that applicants have the ability to save the document to the applicant's local drive, complete the form, and save the form for future applications. CDC made no changes to the forms based on these comments.

B. Consultation Outside the Agency

There has been no consultation outside the agency due to the delegation of responsibilities to the CDC as described herein.

9. Explanation of Any Payment or Gift to Respondents

Respondents will not receive any payment or gift.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

The CIO's Information Systems Security Officer reviewed this submission and determined that the Privacy Act does apply The application requires the applicant's name, mailing address, phone numbers, and email address. The information available on the permit includes the applicant's name, mailing address, phone numbers, and email address. To comply with the Office of Management and Budget (OMB) Memoranda (M) 07-16, Safeguarding Against and Responding to the Breach of Personally Identifiable Information, the attached draft *Federal Register* notice is in the clearance process for the System of Record Notice entitled, *Electronic Federal Select Agent Program portal (eFSAP portal)/Electronic Import Permit Program portal (eIPP portal)*.

The following special safeguards are provided to protect the records from inadvertent disclosure:

Authorized Users: Attempts to gain access by unauthorized individuals are automatically recorded and reviewed on a regular basis. Individuals who have daily access to these records are limited to DSAT staff who have responsibility for conducting regulatory oversight of the importation of infectious biological agents, infectious substances, and vectors of human disease into the United States.

Physical Safeguards: Paper records are maintained in locked cabinets in locked rooms in a restricted access location that is controlled by a cardkey system, and security guard service provides personnel screening of visitors. Electronic data files are password protected and stored in a restricted access location. The computer room is protected by an automatic sprinkler system, numerous automatic sensors (e.g., water, heat, smoke, etc.) are installed, and the appropriate portable fire extinguishers are located throughout the computer room. Computer workstations, lockable personal computers, and automated records are located in secured areas.

Procedural Safeguards: Protection for computerized records includes programmed verification of valid user identification code and password prior to logging on to the system; mandatory password changes, limited log-ins, virus protection, and user rights/file attribute restrictions. Password protection imposes user name and password log-in requirements to prevent unauthorized access. Each user name is assigned limited access rights to files and directories at varying levels to control file sharing. There are routine daily backup procedures and secure offsite storage is available for backup files.

Knowledge of individual tape passwords is required to access tapes, and access to the system is limited to users obtaining prior supervisory approval. To avoid inadvertent data disclosure, a special additional procedure is performed to ensure that all Privacy Act data are removed from computer tapes and/or other magnetic media. A backup copy of data is stored at an offsite location and a log kept of all changes to each file and all persons reviewing the file. Additional safeguards may also be built into the program by the system analyst as warranted by the

sensitivity of the data set.

The DSAT and contractor employees who maintain records are instructed in specific procedures to protect the security of records, and are to check with the system manager prior to making disclosure of data. When individually identified data are being used in a room, admittance at either CDC or contractor sites is restricted to specifically authorized personnel.

Appropriate Privacy Act provisions are included in contracts and the CDC Project Director, contract officers, and project officers oversee compliance with these requirements. Upon completion of the contract, all data will be either returned to CDC or destroyed, as specified by the contract.

Implementation Guidelines: The safeguards outlined above are in accordance with the HHS Information Security Program Policy and FIPS Pub 200, `*Minimum Security Requirements for Federal Information and Information Systems*. Data maintained on CDC's Mainframe and the OPHPR Local Area Network (LAN) are in compliance with OMB Circular A-130, Appendix III.

Security is provided for information collection, processing, transmission, storage, and dissemination in general support systems and major applications.

The CDC will follow its established policies and procedures in releasing and/or withholding trade secret and/or confidential or financial information, in accordance with the Freedom of Information Act.

11. Institutional Review Board (IRB) and Justification of Sensitive Questions

IRB Approval

Institutional Review Board approval is not required. These activities were determined to be public health non-research.

Privacy Impact Assessment Information

The following information is collected from the applicant to receive an import permit as required under 42 CFR 71.54. The information being collected to receive a permit as required under 42 CFR 71.54 includes the applicant’s name, mailing address, phone numbers, and email address. The information available on the permit includes the applicant’s name, mailing address, phone numbers, and email address.

The information is kept in a database which consists of permitted entities importing or subsequently transferring biological agents, infectious substances and vectors of human disease. This database is safeguarded; paper records are kept in locked files. Electronic data files are password protected and stored in a restricted access location. Only a small number of staff within DSAT has access to the information, and disclosure of information is stringently limited.

To comply with the Office of Management and Budget (OMB) Memoranda (M) 07-16,

Safeguarding Against and Responding to the Breach of Personally Identifiable Information, the attached draft *Federal Register* notice is in the clearance process for the System of Record Notice entitled, *Electronic Federal Select Agent Program portal (eFSAP portal)/Electronic Import Permit Program portal (eIPP portal)*.

Sensitive Questions

This data collection does not include personal questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

Annualized burden hours and cost approved in 2018 were calculated based on data obtained from CDC import permit database on the number of permits issued on annual basis since 2015, which was 2,000 respondents. The estimated annualized burden for the 2018 submission was 545 hours. The increased in burden to 1355 hours is due to the increase in the number of respondents and the additional form. There are no costs to respondents except their time.

The estimated annualized burden is 1355 and is an increase from the 2018 submission. The burden includes the addition of the form noted above that accounts for addition of 20 minutes to complete the form.

Table A12A. Estimated Annualized Burden Hours

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 Biological Agents, Infectious Substances and Vectors	Application for Permit to Import Biological Agents, Infectious Substances and Vectors of Human Disease into the United States	2000	1	20/60	667
Applicants Requesting to Import Biological Agents, Infectious Substances and Vectors	Application for Permit to Import Biological Agents, Infectious Substances and Vectors of Human Disease into the United States Guidance	2000	1	10/60	333
Applicants Requesting to	Application for Permit to Import	380	1	50/60	317

Import Biological Agents, Infectious Substances and Vectors	Biological Agents, Infectious Substances and Vectors of Human Disease into the United States-Subsequent Transfer				
Applicants Requesting to Import Live Bats	Application for a Permit to Import Live Bats	10	1	20/60	3
Applicants Requesting to Import Live Bats	Application for a Permit to Import Live Bats Guidance	10	1	10/60	2
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
Total					1,355

Table A12B. Estimated Annualized Burden Costs

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 for Biological Agents – Application and Guidance	2000	1	30/60	1000	28.87	$38,240.00
Subsequent Transfer	380	1	50/60	317	28.87	$ 12,122.08
Applicants for Bats – Application and Guidance	10	1	30/60	5	28.87	$191.20
Applicants	100	1	20/60	33	38.24	1273.89

Requesting to Import Infectious Human Remains into the United States						
Total				1322		$51,815

To estimate costs to respondents, CDC assumed that the hourly burden rate would be evenly split between managerial staff and clerical staff. CDC assumed an average hourly respondent labor rate (including fringe and overhead) of $59.56 for managerial staff (e.g., researchers) and $16.92 for clerical staff (e.g., graduate students/assistants). To calculate the mean hourly rate, we averaged these two figures for an hourly wage rate of $38.24. These rates were obtained from the Bureau of Labor Statistics, from the *2016 Occupational Employment Statistics Survey by Occupation* (http://www.bls.gov/oes/).

13. Estimates of Other Total Annual Cost Burden to Respondents or Record keepers

Respondents incur no capital or maintenance costs. The only costs incurred to respondents are those associated with telephone calls, mailing, and fax transmissions. All of these costs are part of normal business expenses.

14. Annualized Cost to the Government

The total estimated cost for implementing these regulatory activities for fiscal year 2017 is $1,335,495. This estimate includes 6 full-time Federal Employees (FTE) currently working in the import permit program. It also accounts for the program performing 23 inspections per year with two inspectors at a cost of $2000 per inspection. Additional costs incurred by the program are costs as shown below.

FY 2016 Annualized Government Cost

Personnel:	6 FTEs	$ 504,607
Travel:		$ 92,000
Import Permit Database:		$ 697,840
Equipment, supplies and materials:		$ 37,063
Administrative Costs:		$ 3,985
Total:		$ 1,335,495

15. Explanation for Program Changes or Adjustments

The additional form for the importation of human remains allows CDC/IPP to take proactive preparedness precautions to collect information on the importation of human remains that is infected with SARS-CoV-2 for burial.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no plans for tabulation and publication of this data. The data collection is used solely to carry out the provisions of the regulation.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The display of the OMB expiration date is not inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.