U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Print Date: 6/17/24

Title:	Import Permit Applications (42 CFR 71.54) (OMB Control No. 0920-0199)
Project Id:	0900f3eb823c2299
Accession #:	-ORR-6/12/24-c2299
Project Contact:	Albert D Garcia
Organization:	ORR
Status:	**Project In Progress**
Intended Use:	**Project Determination**
Estimated Start Date:	06/12/2024
Estimated Completion Date:	06/30/2034
CDC/ATSDR HRPO/IRB Protocol #:	
OMB Control #:	0920-0199

Determinations

Determination	Justification	Completed	Entered By & Role
HSC: **Does NOT Require HRPO Review**	Not Research / Other *45 CFR 46.102(l)* Other - regulatory compliance	6/12/24	Garcia_Albert D. (asg9) CIO HSC
PRA:			

PRA Applies		6/14/24	Garcia_Albert D. (asg9) OMB / PRA
ICRO: **PRA Applies**	OMB Approval date: 8/13/21 OMB Expiration date: 8/31/24	6/17/24	Zirger_Jeffrey (wtj5) ICRO Reviewer

Description & Funding

Description

Priority:	Standard
Priority Justification:	
CDC Priority Area for this Project:	Not selected
Determination Start Date:	06/12/24
Description:	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 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.
IMS/CIO/Epi-Aid/Lab-Aid/Chemical Exposure Submission:	No
IMS Activation Name:	Not selected
Submitted through IMS Clearance Matrix:	Not selected
Primary Scientific Priority:	Not selected
Secondary Scientific Priority (s):	Not selected
Task Force Responsible:	Not selected
CIO Emergency Response Name:	Not selected
Epi-Aid Name:	Not selected
Lab-Aid Name:	Not selected
Assessment of Chemical Exposure Name:	Not selected

Goals/Purpose	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.
Objective:	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.
Does your project measure health disparities among populations/groups experiencing social, economic, geographic, and/or environmental disadvantages?:	No
Does your project investigate underlying contributors to health inequities among populations /groups experiencing social, economic, geographic, and/or environmental disadvantages?:	No
Does your project propose, implement, or evaluate an action to move towards eliminating health inequities?:	No
Activities or Tasks:	New Collection of Information, Data, or Biospecimens
Target Populations to be Included/Represented:	General US Population
Tags/Keywords:	Biological Control Agents
CDC's Role:	Activity originated and designed by CDC staff, or conducted at the specific request of CDC, or CDC staff will approve study design and data collection as a condition of any funding provided
Method Categories:	Survey
Methods:	# 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. The subpopulation are those 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.
Collection of Info, Data or Biospecimen:	# 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 https://www.cdc.gov/cpr/ipp/applications/index.htm.
Expected Use of Findings/Results and their impact:	# The intended use of the study is to fulfill the requirements promulgated by Health and Human Services under 42 CFR 71.54.
Could Individuals potentially be identified based on Information Collected?	Yes
Will PII be captured (including coded data)?	Yes
Does CDC have access to the identifiers (including coded data)?:	Yes
Is this project covered by an Assurance of	No

Confidentiality?

Does this activity meet the criteria for a Certificate of Confidentiality (CoC)?	No
Is there a formal written agreement prohibiting the release of identifiers?	No

Funding

Funding yet to be added .....

HSC Review

HSC Attributes

Other - regulatory compliance	Yes

Regulation and Policy

Do you anticipate this project will need IRB review by the CDC IRB, NIOSH IRB, or through reliance on an external IRB?	No

Estimated number of study participants

Population - Children	Protocol Page #:
Population - Minors	Protocol Page #:
Population - Prisoners	Protocol Page #:
Population - Pregnant Women	Protocol Page #:

Population - Emancipated Minors

Suggested level of risk to subjects

Do you anticipate this project will be exempt research or non-exempt research

Requested consent process waviers

Informed consent for adults	No Selection
Children capable of providing assent	No Selection
Parental permission	No Selection
Alteration of authorization under HIPAA Privacy Rule	No Selection

Requested Waivers of Documentation of Informed Consent

Informed consent for adults	No Selection
Children capable of providing assent	No Selection
Parental permission	No Selection

Consent process shown in an understandable language

Reading level has been estimated	No Selection
Comprehension tool is provided	No Selection
Short form is provided	No Selection
Translation planned or performed	No Selection
Certified translation / translator	No Selection
Translation and back-translation to/from target language(s)	No Selection
Other method	No Selection

Clinical Trial

Involves human participants	No Selection
Assigned to an intervention	No Selection
Evaluate the effect of the intervention	No Selection

Evaluation of a health related biomedical or behavioral outcome	No Selection
Registerable clinical trial	No Selection

Other Considerations

Exception is requested to PHS informing those bested about HIV serostatus	No Selection
Human genetic testing is planned now or in the future	No Selection
Involves long-term storage of identfiable biological specimens	No Selection
Involves a drug, biologic, or device	No Selection
Conducted under an Investigational New Drug exemption or Investigational Device Exemption	No Selection

Institutions & Staff

Institutions

Will you be working with an outside Organization or Institution? No

Institutions yet to be added .....

Staff

Staff Member	SIQT Exp. Date	CITI Biomedical Exp. Date	CITI Social & Behavioral Exp. Date	CITI Good Clinical Practice Exp. Date	Staff Role	Email	Phone	Organization
Albert Garcia	07/18/2025	10/31/2021	09/15/2026		Co-Investigator	asg9@cdc.gov	404-639-7139	OFFICE OF READINESS AND RESPONSE

Data

DMP

Proposed Data Collection Start Date:	6/12/24
Proposed Data Collection End Date:	6/30/34
Proposed Public Access Level:	Non-Public

Non-Public Details:

Reason For Not Releasing Data:	Other - No utility outside federal gov
Public Access Justification:	Data is for internal use only to fulfill the requirements promulgated by Health and Human Services under 42 CFR 71.54. The data has no utility for the public
How Access Will Be Provided for Data:	Access will not be provided to the public.
Plans for Archival and Long Term Preservation:	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 DRSC 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, Safe-guarding Against and Responding to the Breach of Personally Identifiable Information, the at-tached Federal Register notice was published on August 27, 2020 for the System of Record No-tice entitled, ##Electronic Import Permit Program Portal (eIPP Portal)#

Spatiality

Spatiality (Geographic Locations) yet to be added .....

Dataset

Dataset Title	Dataset Description	Data Publisher /Owner	Public Access Level	Public Access Justification	External Access URL	Download URL	Type of Data Released	Collection Start Date	Collection End Date
Dataset yet to be added...									

Supporting Info

Current	CDC Staff Member and Role	Date Added	Description	Supporting Info Type	Supporting Info
	Zirger_Jeffrey (wtj5) ICRO Reviewer	06/17/2024	NOA 0920-0199 (2024)	Notice of Action	NOA 0920-0199_2021.pdf