



# Project Determination

## Assessing Capacity to Expand Hepatitis C Testing and Treatment in United States Carceral Settings

**Project ID:** 0900f3eb823d4d47  
**Accession #:** NCHHSTP-CIT-4/1/24-544e9  
**Project Contact:** Michtta Jean Louis  
**Organization:** OS/OS/OSI  
**Status:** Pending Regulatory Clearance  
**Intended Use:** Project Determination  
**Estimated Start Date:** 09/26/24  
**Estimated Completion Date:** 09/25/25  
**CDC/ATSDR HRPO/IRB Protocol#:**  
**OMB Control#:**

### Description

#### Priority

Standard

#### Date Needed

07/09/24

#### CDC Priority Area for this Project

Not selected

#### Determination Start Date

06/27/24

#### Description

CDC previously piloted the Comprehensive Understanding of Readiness for Elimination of Hepatitis C in Corrections (Cure-HepC) survey with a partner in 9 jurisdictions. The goal of this contract is to administer the Cure-HepC survey to all 50-state DOCs, the district of Columbia, and a selection of large jails. This project will aid in a targeted approach to eliminate hepatitis C virus in the United States with carceral settings having one of the highest estimated prevalence rates when

compared to the general U.S. population.

**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**

This project aims to increase CDC’s effectiveness in advancing hepatitis C elimination in carceral settings by characterizing hepatitis C burden of disease as well as prevention, testing, and treatment policies at carceral facilities nationally. Carceral settings pose a unique challenge to Hepatitis C elimination in that data, as it relates to hepatitis C virus testing and treatment, is not readily available for analysis to understand the burden of disease within this environment. To our knowledge, CDC does not have a repository of data specifically directed towards hepatitis C within state department of corrections (DOC) or large jails. This contract will provide CDC the opportunity to collaborate with a well-respected community partnership that has built trust within DOC and large jails. CDC will leverage this relationship to administer a survey that will advance the Division of Viral Hepatitis strategic plan to eliminate viral hepatitis in the U.S. The following data will be collected: prevalence of hepatitis C virus, testing methodologies, and treatment practices in state prisons and local jails. Goal 1: Reduce new viral hepatitis infections Goal 2: Reduce viral hepatitis-related morbidity and mortality Goal 3: Reduce viral hepatitis-related disparities

**Objective**

The proposed project aligns with the following goals within the Division of Viral Hepatitis 2025 Strategic Plan. Objective 1.2: Reduce rates of high-risk drug use associated with new viral hepatitis cases Objective 2.2: Increase the number of people with hepatitis C who know their infection status Objective 2.4: Assessing

Capacity to Expand Hepatitis C Testing and Treatment in United States Correctional Systems

**Does your project measure health disparities among populations/groups experiencing social, economic, geographic, and/or environmental disadvantages?**

Yes

**Does your project investigate underlying contributors to health inequities among populations/groups experiencing social, economic, geographic, and/or environmental disadvantages?**

Yes

**Does your project propose, implement, or evaluate an action to move towards eliminating health inequities?**

Yes

**Activities or Tasks**

New Collection of Information, Data, or Biospecimens; Programmatic Work

**Target Population to be Included/Represented**

General US Population; Prisoners

**Tags/Keywords**

Hepatitis C Antibodies; Hepatitis C Antigens; Hepatitis C, Chronic; Hepatitis C; Hepatitis C, incarcerated persons; Hepatitis C, prison; Hepatitis C, jail

**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; CDC employees will participate as co-authors in presentation(s) or publication(s); CDC employees will provide substantial technical assistance or oversight; CDC is providing funding

**Method Categories**

Needs Assessment; Survey

**Methods**

Members of the American Correctional Association (ACA) shall be notified of an anonymous voluntary survey via email conducted by ACA. The email will contain the purpose of the survey and instructions for completing the survey, and how the information will be protected. The survey will take approximately 30-minutes to complete. We would like to receive 100% completion from at least 101 state department of corrections prisons and jails. Respondents can complete the survey via an online survey instrument or an interviewer-administered survey via telephone or videoconferencing.

**Collection of Info, Data, or Bio specimens**

A web-based platform will be used to administer the survey. The survey will be administered over the course of time, as determined by the vendor, to ensure close to 100% response rate. No individual-level or personally identifying information (e.g. name, date of birth) will be collected. The following data will be collected: state prisons and local jails will be classified on a regional and state level, respectively, prevalence of hepatitis C virus, testing methodologies, and treatment practices in state prisons and local jails. Respondents are clinical directors or their designee for each prison or jail.

**Expected Use of Findings/Results and their impact**

Data from this project will be used to inform program planning and evaluation of prevention programs that aim to reduce new viral hepatitis infections, reduce viral

hepatitis-related morbidity and mortality and reduce viral hepatitis-related disparities. The data collected will establish a system for ongoing program evaluation and improvement and allows for data-driven resource allocation to areas of greatest need.

**Could Individuals potentially be identified based on Information Collected?**

No

## Funding

Funding Type	Funding Title	Funding #	Original Fiscal Year	# of Years of Award	Budget Amount
CDC Contract	ACA Sole Source SAP for Hep C in Prisons		2024	1	249999.99

## HSC Review

### HSC Attributes

**Other - This activity has been reviewed by NCHHSTP OADS and was determined to not meet the definition of research as defined in 46.102(I). The purpose of this activity is to increase CDCs effectiveness in advancing hepatitis C elimination in carceral settings by characterizing hepatitis C burden of disease as well as prevention, testing, and treatment policies at carceral facilities nationally. The activity is not designed to develop or contribute to generalizable knowledge. Major changes (amendments) should be submitted for re-review to ensure the changes do not affect this determination.**

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

Will you be working with an outside Organization or Institution? Yes

## Institutions

Institution	FWA #	FWA Exp. Date	Funding	Funding Restriction Amount
American Correctional Association			ACA Sole Source SAP for Hep C in Prisons	

Institution	Funding Restriction Percentage	Funding Restriction Reason	Funding Restriction has been lifted
American Correctional Association			

Institution	Institution Role(s)	Institution Project Title	Institution Project Tracking #	Prime Institution
American Correctional Association	Designing or Developing Project and/or Data Collection Instrument(s); Obtaining, Storing or Transferring Non-Identifiable Private Information or Non-Identifiable Biospecimens; Other - Administering survey			

Institution	Regulatory Coverage	IRB Review Status
American Correctional Association	IRB Review is Not Required	

Institution	Registered IRB	IRB Registration Exp. Date	IRB Approval Status
American Correctional Association			

Institution	IRB Approval Date	IRB Approval Exp. Date	Relying Institution IRB
American Correctional Association			

Staff								
Staff Member	SIQT Exp. Date	Citi Biomedical Exp. Date	Citi Social and Behavioral Exp. Date	Citi Good Clinical Exp. Date	Staff Role	Email	Phone #	Organization/Institution
Lindsey Sizemore	10/12/2026				Technical Monitor	ocr1@cdc.gov	- -	PREVENTION BRANCH
Michtta Jean Louis	08/04/2026				Technical Monitor	qdy2@cdc.gov	954-232-2801	CLINICAL INTERVENTION TEAM
Steven Hogan	07/24/2026				Contract Officer	vjn5@cdc.gov	404-718-	PROGRAM TEAM

Staff								
Staff Member	SIQT Exp. Date	Citi Biomedical Exp. Date	Citi Social and Behavioral Exp. Date	Citi Good Clinical Exp. Date	Staff Role	Email	Phone #	Organization/Institution
					Representative	ov	8741	
TerriCatlett	n/a	n/a	n/a	n/a	Institution Primary Contact	terric@aca.org		American Correctional Association

DMP	
<b>Proposed Data Collection Start Date</b>	09/26/24
<b>Proposed Data Collection End Date</b>	09/25/25
<b>Proposed Public Access Level</b>	Non-Public
<b>Reason for not Releasing the Data</b>	Other- Data is for programmatic work
<b>Public Access justification</b>	Data from this project will be used to inform program planning and evaluation of prevention programs that aim to reduce new viral hepatitis infections, reduce viral hepatitis-related morbidity and mortality and reduce viral hepatitis-related disparities. The data collected will establish a system for ongoing program evaluation and improvement and allows for data-driven resource allocation to areas of greatest need.
<b>How Access Will Be Provided for Data</b>	Access to the data can be requested through a concept proposal review process as outlined in the data management plan developed by CDC and vendor.
<b>Plans for archival and long-term preservation of the data</b>	CDC will retain and store a dataset, consistent with existing CDC standards for long-term preservation of data or 5-years, whichever is greatest.

Spatiality (Geographic Location)		
Country	State/Province	County/Region
United States		

## Determinations

Determination	Justification	Completed	Entered By & Role
HSC: <b>Does NOT Require HRPO Review</b>	Not Research / Other  <i>45 CFR 46.102(l)</i>  Other - This activity has been reviewed by NCHHSTP OADS and was determined to not meet the definition of research as defined in 46.102(l). The purpose of this activity is to increase CDCs effectiveness in advancing hepatitis C elimination in carceral settings by characterizing hepatitis C burden of disease as well as prevention, testing, and treatment policies at carceral facilities nationally. The activity is not designed to develop or contribute to generalizable knowledge. Major changes (amendments) should be submitted for re-review to ensure the changes do not affect this determination.	06/26/24	Dodson_Janella R. (jhd7) CIO HSC
PRA: <b>PRA Applies</b>		06/27/24	Bonds_Constance (akj8) CTR OMB/PRA Coordinator