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

Print Date: 2/15/23

Title:	PS22-2208 Component 1 SSP Survey
Project Id:	0900f3eb81fd8d55
Accession #:	NCHHSTP-SIT-9/16/22-d8d55
Project Contact:	Renee M Brocker
Organization:	NCHHSTP/DVH/SIT
Status:	**Project In Progress**
Intended Use:	**Project Determination**
Estimated Start Date:	11/01/2022
Estimated Completion Date:	09/30/2027
CDC/ATSDR HRPO/IRB Protocol #:	
OMB Control #:	0920-1359

Determinations

Determination	Justification	Completed	Entered By & Role
HSC: **Does NOT Require HRPO Review**	Not Research - Public Health Surveillance *45 CFR 46.102(l)(2)*	11/8/22	Dodson_Janella R. (jhd7) CIO HSC
PRA: **PRA Applies**		11/9/22	Bonds_Constance (akj8) CTR OMB/PRA Coordinator

ICRO: **PRA Applies**	OMB Approval date: 3/18/22 OMB Expiration date: 12/31/24	11/9/22	Zirger_Jeffrey (wtj5) ICRO Reviewer

Description & Funding

Description

Priority:	Standard
Date Needed:	11/01/2022
Determination Start Date:	09/21/22
Description:	The CDC, with the support of Research Triangle Institute (RTI), the National Harm Reduction Coalition, the University of Washington, Heluna Health, and the North American Syringe Exchange Network (NASEN), plan to conduct the National Syringe Service Program (SSP) Evaluation, an annual survey with syringe services programs (SSPs) nationwide. The project does not require human subjects approval, as it is program surveillance for which CDC plans to administer an ongoing, annual survey. PRA does apply and the 60-day FRN was published on February 25, 2021. OMB approval for the National Syringe Service Program (SSP) Evaluation was obtained 12/15/2021 and expires 12/31/2024. This program surveillance effort is based on the Dave Purchase Memorial Survey which is a national survey of syringe services programs (SSPs) that collects data on program operations and outcomes. The survey was conducted annually by Dr. Don Des Jarlais and his staff and NASEN since the mid-1990s, but the survey has not been conducted consistently since 2014. In 2022 CDC conducted this national SSP survey, with the support of University of Washington, Dr. Don Des Jarlais, and NASEN. This project aims to improve the ability of CDC and local and state partners to monitor SSPs nationally, with the overall goal of supporting, sustaining, and improving SSPs nationwide. Over the course of the next two years, three years, the the National Syringe Service Program Survey will continue to be conducted annually by CDC and its partners to help build a stable foundation for SSP monitoring, establish a system for program improvement, and ensure quality service delivery at SSPs nationwide.
IMS/CIO/Epi-Aid/Lab-Aid/Chemical Exposure Submission:	No
IMS Activation Name:	Not selected
Primary Priority of the Project:	Not selected
Secondary Priority(s) of the Project:	Not selected
Task Force Associated with the Response:	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
	The primary purpose of the program surveillance project is to strengthen and improve the capacity of SSPs to conduct regular monitoring to ensure that comprehensive prevention services are provided to meet the needs of PWID and reduce infectious

Goals/Purpose	disease and other harms related to injecting drug use (IDU). The primary goal of the project is to: 1) assess and monitor Syringe Services Programs (SSP) operational characteristics and services, client characteristics and drug use patterns, funding resources, community relations, and key operational and programmatic successes and challenges, and 2) support timely analysis and dissemination of national program evaluation survey findings.
Objective:	The objectives of the project are to: 1) collect data on program operations including service delivery, and characteristics to support quality service delivery at SSPs nationwide; and 2) to inform planning and evaluation of prevention programs that aim to reduce injection-related adverse health outcomes among people who inject drugs.
Does this project include interventions, services, or policy change work aimed at improving the health of groups who have been excluded or marginalized and /or decreasing disparities?:	Yes
Project does not incorporate elements of health equity science:	Not Selected
Measuring Disparities:	Yes
Studying Social Determinants of Health (SDOH):	Yes
SDOH Economic Stability:	Not Selected
SDOH Education:	Not Selected
SDOH Health Care Access:	Yes
SDOH Neighborhood and Environment:	Not Selected
SDOH Social and Community Context:	Yes
SDOH Indices:	Not Selected
Other SDOH Topics:	Not Selected
Assessing Impact:	Not Selected
Methods to Improve Health Equity Research and Practice:	Not Selected
Other:	Not Selected
Activities or Tasks:	New Collection of Information, Data, or Biospecimens
Target Populations to be Included/Represented:	Other - Syringe Service Programs
Tags/Keywords:	HIV ; Hepatitis C ; Drug Users
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:	Survey

Methods:	SSPs in the United States, who have registered in the NASEN Directory and given permission to be contacted by email, will be sent a letter of invitation to complete an approximately 35-minute survey about their program. Potentially up to 600 SSPs will be reached annually. A letter of invitation will be sent to SSPs, and will include a description of the survey, instructions for completing the survey, web-link to the survey itself (if program managers/staff would prefer to complete it that way), and details about how to access the incentive upon completion of the CDC National Syringe Service Program Evaluation Survey. SSPs can complete the survey two ways: Option 1: The SSP can enter responses to survey questions via a secure, web-based application, for example the Research Electronic Data Capture (REDCap) for which a survey link will be provided in the letter of invitation. Option 2: The SSP can provide responses to survey questions via phone or videoconferencing, using a scheduling link provided to coordinate date and time with an interviewer. The recipient will compile the data, clean it, and run an initial surveillance report analysis. A final dataset will be securely transferred to CDC where it will be checked for accuracy and stored for additional analyses.
Collection of Info, Data or Biospecimen:	A program manager or staff member designated by the SSP will complete a 35-minute program survey via the options described above. A web-based application like REDCap that allows both self-administered and interviewer-administered survey data collection will be used for all data entry and storage. The program survey will be administered over the course of approximately 3 months and will be administered annually. The survey will collect the program name and location. No individual-level or personally identifying information (e.g., name, date of birth, social security number) will be collected. The main data collection components for this program survey include basic aggregate client characteristics and program operational characteristics, service delivery, funding resources, community relations, operational successes and challenges, and impact to operations and services due to COVID-19. The respondents are an SSP program manager or their designee. Respondents may refuse to answer questions or stop participation at any time without penalty.
Expected Use of Findings/Results and their impact:	The data collected will establish a surveillance system for ongoing program monitoring and evaluation of SSPs. Data will also help ensure quality service delivery at SSPs nationwide.
Could Individuals potentially be identified based on Information Collected?	No

Funding

Funding Type	Funding Title	Funding #	Original Budget Yr	# Years Award	Budget Amount
CDC Cooperative Agreement	Strengthening Syringe Service Programs	CDC-RFA-PS22-2208	2022	5	

HSC Review

Regulation and Policy

Do you anticipate this project will be submitted to the IRB office	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	Protocol Page #:

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 HIPPA 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

Name	FWA #	FWA Exp Date	IRB Title	IRB Exp Date	Funding #
Research Triangle International					CDC-RFA-PS22-2208
North American Syringe Exchange Network					CDC-RFA-PS22-2208

Heluna Health					CDC-RFA-PS22-2208
University of Washington					CDC-RFA-PS22-2208
National Harm Reduction Coalition					CDC-RFA-PS22-2208

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
Alex Kral	n/a	n/a	n/a	n/a	Technical Monitor	akral@rti.org		Research Triangle International
Barrot Lambdin	n/a	n/a	n/a	n/a	Principal Investigator	blambdin@rti.org		Research Triangle International
Don Des Jarlais	n/a	n/a	n/a	n/a	Technical Monitor	don.desjarlais@nyu.edu		
Elizabeth Adams	n/a	n/a	n/a	n/a	Program Lead	etroutmanadams@rti.org		Research Triangle International
Erica Browne	n/a	n/a	n/a	n/a	Program Lead	ebrowne@rti.org		Research Triangle International
Hansel Tookes	n/a	n/a	n/a	n/a	Technical Monitor	hetookes@med.miami.edu		
Jamie Humphrey	n/a	n/a	n/a	n/a	Program Lead	jhumphrey@rti.org		Research Triangle International
Julia Brinton	n/a	n/a	n/a	n/a	Technical Monitor	jbrinton@rti.org		Research Triangle International
Kathryn Greenwell	n/a	n/a	n/a	n/a	Project Coordinator	kgreenwell@rti.org		Research Triangle International
Lynn Wenger	n/a	n/a	n/a	n/a	Program Lead	lynndee@rti.org		Research Triangle International
Monica Adams	05/21/2024		10/29/2017		Principal Investigator	ydy7@cdc.gov	404-718-5092	STRATEGY AND IMPLEMENTATION TEAM

Nathan Furukawa	06/05 /2023	04/23/2024		07/22/2021	Project Officer	nmt6@cdc.gov	404-718-7205	STRATEGY AND IMPLEMENTATION TEAM
Orisha Bowers	06/05 /2023	04/23/2024		07/22/2021	Technical Monitor	bowers@harmreduction.org		National Harm Reduction Coalition
Paul LaKosky	n/a	n/a	n/a	n/a	Technical Monitor	paul@nasen.org		North American Syringe Exchange Network
Renee Brocker	n/a	n/a	n/a	n/a	Project Officer	odj7@cdc.gov	614-849-8933	STRATEGY AND IMPLEMENTATION TEAM
Ricky Bluthenthal	06/05 /2023	04/23/2024		07/22/2021	Technical Monitor	rbluthen@usc.edu		
Sara Glick	n/a	n/a	n/a	n/a	Technical Monitor	snglick@uw.edu		University of Washington
Sheila Patel	n/a	n/a	n/a	n/a	Co-Investigator	svpatel@rti.org		Research Triangle International
Stephanie Prohaska	n/a	n/a	n/a	n/a	Technical Monitor	stephanie@nasen.org		North American Syringe Exchange Network
Talia Pindyck	n/a	n/a	n/a	n/a	Principal Investigator	nrb1@cdc.gov	404-718-6809	STRATEGY AND IMPLEMENTATION TEAM
Terry Morris	06/05 /2023	04/23/2024		07/22/2021	Technical Monitor	tmorris.contractor@rti.org		Heluna Health

Data

DMP

Proposed Data Collection Start Date: 1/1/23

Proposed Data Collection End Date: 9/30/27

Proposed Public Access Level: Public

Public Access Justification:	These data may help public health officials and partners in public health planning, implementation, and evaluation. The data do not contain any individual identifying information and is not protected by an assurance of confidentiality. CDC will not receive the names of SSPs. SSPs may be identifying based on the geographical information for SSPs in a rural or underserved area. A concept proposal review committee will review data requests to determine what level of granularity for location is needed to complete the analysis.
How Access Will Be Provided for Data:	Access to the data can be requested through a concept proposal review process as outlined in the data management plan developed by the CDC and the awardee.
Plans for Archival and Long Term Preservation:	After completion of the project performance period, the awardee will retain a copy of the data based on a data sharing agreement and data management plan generated under the cooperative agreement with the CDC. The CDC will also retain and store a clean dataset, consistent with existing CDC standards for long-term preservation of data.

Spatiality

Country	State/Province	County/Region
United States		

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	11/09/2022	NOA 0920-1359 (2022)	Notice of Action	0920-1359_2022.pdf

Current	Furukawa_Nathan (nmt6) Project Contact	09/21/2022	NOFO	Notice of Funding Opportunity	CDC-RFA-PS22-2208 (Revised Final).pdf