Injection Drug Use Surveillance Project

OMB Control Number: 0920-New

Supporting Statement A

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Table of Contents

List of Attachments

Attachment number	Document description
1	Authorizing Legislation
2	60-Day Federal Register Notice (FRN)
2A	Public Comment to 60 day FRN
3	Eligibility Screening Form
4	Model Recruitment Coupon
5	Model Recruiter Training Script
6	Model Project Permission Form
7	IDU Survey
8	Recruitment Coupon Spreadsheet
9	Assurance of Confidentiality
10	Project Determination
11	Screenshots of IDU Survey in REDCap (Web-based application)
12	Sample Analysis Tables

Goals of the project: The primary purpose of the IDU Surveillance Project (IDU-SP) is to develop a surveillance system to monitor drug use risk and prevention behaviors and the infectious disease consequences of high-risk drug use in 6-30 select urban and non-urban areas of the United States that have been impacted by the opioid crisis. Such a surveillance system is urgently needed to develop prevention efforts and policy. The specific objectives of the project are to assess the following among persons who use drugs (i.e., via injecting and non-injecting routes of administration) who are recruited in syringe services programs (SSPs) and through peer-driven recruitment: 1) drug use and sex risk behaviors, injection risk networks, receipt of prevention services, and barriers to prevention and care; and 2) the prevalence of HIV and Hepatitis C virus (HCV) infections.

Intended use: Data from the IDU-SP will be used to inform planning and evaluation of prevention programs at the local and national level that aim to reduce adverse health outcomes of injecting and non-injecting drug use and to contribute to the overall opioid crisis response efforts. Data from the IDU-SP will also be used to establish an ongoing surveillance system in the U.S. to monitor trends in drug use and the infectious disease consequences of drug use.

Methods to be used to collect data:
Clients of SSPs and their peers who meet eligibility criteria (i.e. English speaking, ≥18 years of age, able to give permission to participate in project, and injected drugs in the past 6 months OR used injectable drugs other than marijuana via non-injecting routes in the past 6 months) will complete about a 30 minute survey using the Research Electronic Data Capture (REDCap) system, a secure web-based application for administering online surveys. The survey will include questions on drug use and sex risk behaviors, risk networks, transitions from non-injection drug use to drug injection, drug treatment history, history of drug-use-related adverse health outcomes, such as overdose, experiences with law enforcement, experiences with violence, HIV and HCV testing experience, and use of prevention and health care services. Lastly, participants will be offered anonymous HIV and HCV testing in conjunction with the survey, which they may refuse with no effect on participation in the survey.

The subpopulation to be studied: The project will involve a two-stage sampling approach. First, 6-30 SSPs will be selected to ensure geographic diversity and representation of key program characteristics, such as syringe distribution model (needs-based vs all other) and length in operation (<5 years, 5 years or longer). Second, SSP clients and their drug using peers will be recruited through a combination of random recruitment at SSPs and peer-driven recruitment to partake in a survey, as well as HCV and HIV testing.

How data will be analyzed: Data will be analyzed using Analytic Software & Solutions (SAS) software or other appropriate statistical packages. Univariate and bivariate statistics and multivariable regression methods will be used to address the objectives of the project.

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC), National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) requests approval for 3 years for new data collection called "National Harm Reduction Technical Assistance and Syringe Services Program (SSP) Monitoring and Evaluation," Notice of Funding Opportunity, CDC-RFA-PS19-1909.

The IDU-SP aims to conduct an IDU surveillance project in 6-30 SSPs among people who inject drugs (PWID) and their injecting or non-injecting peers, who may be at high risk for IDU. Data from this project will be used to inform planning and evaluation of prevention programs that aim to reduce injection-related adverse health outcomes and to establish an ongoing surveillance system of injection drug use and associated risks, at the national and local levels. The two main objectives of the IDU-SP are to: 1) conduct surveillance in collaboration with SSPs among PWID and their drug-using peers, to assess such topics as their injection use trends, risk behaviors, injection risk networks, receipt of prevention services, and barriers to prevention and care; and 2) estimate the prevalence of HIV and HCV infections among PWID and their drug using peers.

Background

The opioid crisis in the U.S. has led to steep increases in overdose (1), HCV incidence (2) and HIV clusters and outbreaks among people who inject drugs (PWID)(3-6). These alarming trends indicate an urgent need to strengthen interventions to prevent morbidity and mortality and transmission of infectious disease among PWID. Syringe services programs (SSPs) are evidence-based, highly effective prevention programs that have expanded in many areas in the United States to respond to the increasing needs of providing HIV and HCV prevention and other health and social services to PWID and their communities. Due to an increase in HCV and HIV related to IDU (7,8), it is now critical to understand current patterns of IDU for the prevention of these infectious diseases and other injection related harms. Data to inform these prevention efforts are needed nationally, particularly from non-urban settings that have experienced increases in injection drug use and where current surveillance activities are non-existent or limited (9).

No systematic data has been collected from PWID nationally. Large population surveys, such as the Substance Abuse and Mental Health

Services Administration (SAMHSA National Survey on Drug Use and Health), sample from non-institutionalized populations and have a very small proportion reporting a history of IDU (10). The National HIV Behavioral Surveillance (NHBS) system is an ongoing surveillance system that samples PWID across 20-23 metropolitan statistical areas (MSAs) in the U.S. to collect information on behaviors and HIV infection. However, the system is limited to large urban centers with high HIV prevalence and thus misses information from non-urban areas and other communities highly impacted by the opioid epidemic (11). The SAMHSA Treatment Episode Dataset only captures those who enter substance use treatment and report injection drug use as primary factor for entering treatment (12). There is no existing national survey that specifically samples from SSPs, and there is little information about the impact these programs have on the people who use them. Given the limitations of these survey data and the need to better understand the syndemics of drug use and infectious disease, this project proposes to work with a grantee to fill in the gaps on drug use and related behavioral data from PWID and their drug using peers. The IDU-SP is unique in its sampling strategy and scope. Although it is currently funded as a one-time survey, should more funds be made available, it will be implemented at more SSPs, either annually or biannually, and could also provide invaluable information about trends in drug use, risk behaviors and infectious disease in high risk populations in the U.S. These data will be used to inform best practices for SSPs, identify gaps in services, and demonstrate the impact of SSPs on the health of PWID.

This proposed information collection is authorized under Section 301(a) of the Public Health Services Act (42.U.S.C.241) **(Attachment 1).**

2. Purpose and Use of Information Collection

The primary purpose of the IDU-SP is to develop an IDU surveillance system that collects information on injection use patterns, drug use and sex risk behaviors, and infectious diseases to inform planning and evaluation of prevention programs, and to reduce injection-related adverse health outcomes.

This project will develop partnerships with SSPs to collect surveillance data to understand HIV and HCV risk in communities highly impacted by the opioid crisis, to collect information to strengthen SSPs effectiveness in reducing infectious disease

related to drug injection, and to inform other prevention efforts for PWID, their drug using peers, and their communities. As SSPs continue to expand services and build local partnerships, these programs could be ideal long-term partners for national and local surveillance efforts.

The IDU-SP will employ a two-stage sampling framework. In the first stage, between 6-30 SSPs will be selected to ensure representation on the following criteria: 1) setting (urban, suburban, and rural), 2) U.S. Census region (East, South, Midwest, and West), 3) length in operation (<5 years, 5 years or longer), 4) syringe distribution model (needs-based vs all other), and 5) health department affiliation (yes, no). The sample of potential SSPs will be selected from a publicly available directory of all known SSPs in the U.S. maintained by the North American Syringe Exchange Network (NASEN; https://nasen.org). SSPs will be not considered if they are in MSAs that currently participate in the CDC's National HIV Behavioral Surveillance (NHBS) system. SSPs will also be excluded from the selection process if they are not located in jurisdictions with CDC concurrence of determination of need for SSPs (DON; https://www.cdc.gov/hiv/risk/ssps-jurisdictions.html) as specified in the funding announcement (PS19-1909) for this project.

In the second stage of sampling, SSP clients and their drug using peers will be recruited through a combination of direct recruitment at the SSP and peer-driven recruitment. This sampling strategy was designed to ensure sufficient participation by SSP clients to provide valuable information to each participating SSP and to reach deeper into the networks of persons who use drugs in these communities to understand injection drug use related risks and access to prevention services. At each of the 6-30 selected SSPs, recruitment will begin with inviting SSP clients to participate in the IDU-SP. Persons who meet the IDU-SP eligibility criteria (**Attachment 3**) and complete the survey (**Attachment 4**) will be asked to recruit others they know who use drugs (other than marijuana) via injecting and non-injecting routes. This peer-driven strategy for recruitment is similar to respondent-driven sampling (RDS)(13,14). As in RDS, participants will be given up to 5 coupons to recruit their peers (**Attachment 4**). The recruited peers who meet the IDU-SP eligibility criteria and complete the survey will be given up to 5 coupons to recruit their peers, and this recruitment process will continue until the project sample size is reached. To ensure standardization of recruitment methods, project staff will use a recruitment

training script (**Attachment 5**) to explain who should be recruited. Recruitment will be monitored on an ongoing basis to ensure that at least 50 SSP clients (recruited at SSP and through peer-driven recruitment) are included in the sample; once this goal is reached, direct recruitment at the SSP will stop and only peer-driven recruitment will continue until the total sample of 300 participants per site is reached.

A short screener to assess eligibility for project participation in the IDU-SP (**Attachment 3**) will be administered. Eligibility criteria will include: 1) 18 years or older; 2) injected drugs in the past 6 months OR used injectable drugs other than marijuana via non-injecting routes in the past 6 months; 3) English speaking; 4) able to give permission to participate; and 5) no previous participation in this survey. Eligible persons who give permission to participate (**Attachment 6**) will be asked to complete about a 30 minute survey using the Research Electronic Data Capture (REDCap) software via a computer or a handheld device (e.g., tablet). REDCap is a secure web-based application that includes a self-administered component with an audio-recording feature that allows questions to be heard using headphones so that participants can answer questions privately (**Attachment 7**). The beginning and closing sections of the survey will be interviewer-administered to ensure that participants understand how to take this survey. Participants will have an option to use the self-administered feature of the survey with an audio recording to complete sections of the survey that ask about potential sensitive information (e.g., drug use, sex practices). In addition to the survey, participants will be offered anonymous, rapid HIV and HCV testing, which they may refuse with no effect on participation in the survey. Those who provide verbal permission to HIV and HCV testing will also be asked to allow storage of left-over blood specimens via dried blood spots (DBS) for additional future testing. Participants may refuse DBS specimen collection with no effect on participation in the survey or the choice to get tested for HIV and HCV. The project goal is for 90% or more of participants to agree to testing. Participants who screen positive for HIV or HCV will be offered linkage to available care and treatment. All participants will be offered referrals to health and social services based on participant need and local availability. Similar to another OMB approved surveillance project of people who inject drugs (OMB # 0920-0770; Expiration: 01/31/2023), HIV and HCV testing are not included in the burden estimates of this surveillance project as it is considered a clinical procedure.

The COVID-19 pandemic may impact the timing of sampling and

survey administration; however, project partners will ensure that sampling of SSPs takes place with the most up-to-date information about SSP closures and re-openings. In addition, respondents of this data collection will not be engaged in the COVID-19 response, either directly or as support. However, respondents' need for SSP services will continue throughout the pandemic, and therefore this data collection remains critical to inform planning and evaluation of prevention programs for PWID, and to reduce injection-related adverse health outcomes during and after the pandemic.

3. Use of Improved Information Technology and Burden Reduction

Data will be collected electronically to minimize burden to participants and interviewers. Data on recruitment coupons that link recruiters and recruits during the peer-driven component of recruitment in this project will be entered directly into a spreadsheet on a computer designed for this purpose (**Attachment 8**). By entering data directly into the on-line REDCap computer system, the efficiency of data collection is improved as compared to using paper and then transferring that data into a computer database. The recruitment coupon spreadsheet will also reduce the time and effort to validate coupons and track payments of incentives. During a participant's visit, data can be called up efficiently through use of search terms, such as by coupon number. With logic checks and range values programmed in, the quality of the data is improved. Data from the recruitment coupons spreadsheet linking recruiters and recruits will also be used in analyses.

The recipient awarded by CDC to oversee this project will conduct training and site visits to provide instructions and technical assistance on how to archive the collected data and share the data. The award recipient will regularly convene 'lessons learned' meetings to understand the problems that can occur with the survey that is used for conducting the interviews. Automated edit checks will be built into the computer software programs as a further quality control measure. Provision of electronic data collection software, training and technical assistance will help to reduce the burden on conducting IDU surveillance project.

The project data files will be transferred directly to the RedCap server and accessed by the Grant Recipient. All data files must be transmitted to CDC using the Secure Data Network (SDN).

4. Efforts to Identify Duplication and Use of Similar Information

We reviewed currently-funded programs and did not identify

potential areas of duplication. We are not aware of any department or agency that rigorously or systematically collects or maintains data on risk behavioral data from PWID and persons who do not inject drugs but are at risk of initiating drug injection, both in urban and non-urban settings. The National HIV Behavioral Surveillance (NHBS) system (OMB 0920-0770) collects behavioral data from PWID, but it is limited to up to 25 large urban areas with high HIV prevalence.

5. Impact on Small Businesses or Other Small Entities

This data collection will not involve small businesses.

6. Consequences of Collecting the Information Less Frequently

Data collection activities will occur during calendar year 2020. It is currently funded as a project, but it is expected that if successful, this effort will continue beyond this initial funding period. If the IDU-SP was not implemented, we would continue to lack a systematic way to examine infectious disease, overdose, and other consequences of high-risk drug use among people who inject drugs and their drug using peers.

There are no legal obstacles to reduce the burden.

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

This request fully complies with the guidelines of 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 to solicit public comments was published in the Federal Register on 03/09/2020, Volume 85, Number 46, Pages 13655-13656 (**Attachment 2**). One non-substantive comments was received. No CDC response was sent because contact information was not provided.

9. Explanation of any Payment or Gift to Respondents

Participants will be given approximately $20 for participation in

the IDU survey, $10 for taking voluntary HIV and HCV tests, $10 for each peer recruited (up to 5) into the IDU-SP as a token of appreciation for participation, but no more than $80. The specific amounts will be determined by the award recipient and local partners based on local standards. In sampling methods that rely on peer-driven recruitment, participants receive a token of appreciation for participating as a respondent and a reward for successfully recruiting one or more of their peers. Recruiter rewards of approximately $10 are standard in studies using this sampling methodology. A dual-incentive system is a standard part of peer-driven recruitment in which participants receive a token of appreciation for completing the surveillance activities and for recruiting their peers. Research indicates that providing a token of appreciation to participants helps raise response rates for long, sensitive, in-person surveys (15). A token is also provided to persons who participate in other HIV-related data collection conducted by CDC, such as the National HIV Behavioral Surveillance (NHBS) system (OMB # 0920-0770; Expiration: 01/31/2023), an ongoing surveillance system that samples PWID across 20-23 MSAs in the U.S., to collect information on behaviors and HIV infection, and offers a $25 token for participation. The Medical Monitoring Project (OMB 0920-0740, exp. 6/30/2021), which collects sensitive information from HIV-positive persons, also utilizes incentives to reduce nonresponse. Participants in the Medical Monitoring Project are offered $25 for their time. A token of appreciation of a similar amount was used in the Supplement to HIV/AIDS Surveillance (SHAS) project (OMB 0920-0262, exp. 06/30/2004).

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

The CDC Information Systems Security Officer (ISSO) has assessed this package for applicability of 5 U.S.C. § 552a, and determined that the Privacy Act does not apply. The data collected will be anonymous, in that name or social security number are not collected. Data collected, both locally and at CDC, are stored and accessed by a survey identification number. Other data collected, while sensitive, are not personally identifying; these survey questions are described in Section 11.

In addition to limiting the amount of personally identifying information collected, this submission is covered by an Assurance of Confidentiality for HIV/AIDS surveillance data (**Attachment 9**). The Assurance provides the highest level of legal confidentiality

protections to the individual persons who are the subject of this data collection, and to the individuals and organizations responsible for data collection. The terms of the Assurance of Confidentiality reflect the collective experience of CDC, health departments, and the Council of State and Territorial Epidemiologists with respect to the collection, electronic transmission, and dissemination of HIV/AIDS surveillance data. The Assurance includes established policies and procedures governing all aspects of data collection and de-identification, physical security for paper forms and records, electronic data storage and transmission, and the release of aggregate data in forms that cannot be linked back to individual participants. The protections afforded by the Assurance of Confidentiality last forever, and endure even after the respondent's death.

The Assurance of Confidentiality is enforced with appropriate training and contractual agreements which clarify the responsibilities of all participants in HIV/AIDS surveillance activities who have access to directly identifiable data or to data that are potentially identifiable through indirect means. State and local health department personnel who conduct HIV/AIDS surveillance are subject to the confidentiality obligations described in the CDC guidelines for the security and confidentiality of HIV/AIDS Reporting System (HARS) data (http://www.cdc.gov/hiv/topics/surveillance/index.htm) and are required to undergo security and confidentiality training. Interviewers and data managers will undergo the same security and confidentiality training as required for health department staff. CDC's Procurement and Grants Office will require the inclusion of 308(d) clauses in any HIV/AIDS support services work done by contractors (e.g., data analysis, computer programming, LAN support). All CDC permanent employees and their contractors will be required to attend annual confidentiality training, to sign a Nondisclosure Agreement and to update their confidentiality agreements on an annual basis. Contractors must sign a "Contractor's Pledge of Confidentiality." Access to HIV/AIDS surveillance data maintained at CDC is restricted to authorized personnel who have signed the "Agreement to Abide by Restrictions on Release of Data." CDC-funded cooperative agreements to state and local health departments reference the Assurance of Confidentiality as a condition of award.

An internet-based system will be used to transmit HIV/AIDS surveillance data to CDC. This system is referred to as the Secure Data Network (SDN). Databases submitted through the SDN must be encrypted before being sent to CDC. Encryption security for all data must meet the current National Institute of

Standards and Technology (NIST) Federal Information Processing Standards (FIPS), which meet or exceed Advanced Encryption Standards (AES). See the document "Technical Guidance for HIV/AIDS surveillance Programs, Volume III: Security and Confidentiality Guidelines" for further information (www.cdc.gov/hiv/surveillance.htm).

A number of required protections ensure the security of the data on the portable computers (e.g., tablets). The portable computers are solely used for data collection activities. Portable computers are protected by using a coded password only known by authorized project staff. The portable computers must be kept with the staff at all times when in the field; the computers are collected and secured by the field supervisor after the last survey/interview each day. When not in use in the field, the portable computers are to be locked in a drawer or office.

The project permission process for participants may be fulfilled by obtaining verbal permission from the respondent. All sites must obtain a project permission form from participants and document it in the data collection form on the portable computer. A model project permission form is included as **Attachment 6**. Permission must be given to participate for the survey and HIV and HCV testing separately. Participants may elect to do the survey and not be tested for HIV and HCV; however, they may not be tested without completing the survey. (Persons who only want an HIV test or HCV test may be given information on where to seek an HIV or HCV test elsewhere). In conducting the proposed surveillance activities, participants will be informed that their data will be kept private and secure and that the data will be reported in aggregate format. All surveys/interviews will be conducted by trained staff in a private location where the questions and responses cannot be overheard by others.

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

IRB Approval

The approved Project Determination Form (**Attachment 10**) indicates that because the project is a routine disease surveillance activity, the protocol will not be reviewed by CDC's IRB.

People who inject drugs are at high risk for a host of negative sequelae including infectious diseases such as viral hepatitis and HIV, endocarditis and other bacterial infections, wound

abscesses, cellulitis, and overdose. The mode of transmission necessitates the collection of sensitive data regarding drug use and sexual practices. Other sensitive data are collected because the specific behaviors, experiences or conditions have been shown to be associated with negative consequences of injection drug use or non-injection drug use of injectable drugs (e.g., smoking or snorting heroin). This includes the collection of information about medical information related to infectious disease status, STD diagnosis and testing, hepatitis diagnosis and vaccinations; overdose; history of incarceration; and violence. Questions about race and ethnicity will be asked using OMB's two question format. These questions will be used to report on racial and ethnic disparities that have been well documented in other research on HIV risk and risk behaviors.

Sensitive Questions

Although the information requested from participants is highly sensitive, the IDU-SP cannot be accomplished without their collection. Collection of the data is used to understand barriers to engaging in protective behaviors, to using HIV and viral hepatitis prevention services, and to other services that improve the health of people who use drugs. These data are also used to enhance prevention programs designed to reduce high-risk behaviors in persons most likely to experience the infectious disease consequences of high-risk substance use.

The context in which questions are asked help to overcome their potential sensitivity. Several steps will be taken to minimize sensitivity and reiterate to the respondent the legitimate need for the information:

- Nearly all questions allow for responses of "don't know" or "refuse to answer."
- Project permission form makes it clear that the survey is anonymous and how and by whom the information will be used.
- Project permission form makes it clear that the survey is sponsored by CDC and the grant recipient, and local phone numbers will be provided if the respondent has questions about the survey.
- The survey is carefully organized to lead smoothly from one topic to another. Transitions are made clear to participants and the need for the information explained. Assurances about the privacy and confidentiality of the data are reiterated.
- The use of portable computers (e.g., tablets) for data

collection addresses concerns about privacy the respondent might have (that others can see their answers).
- The payment of a token of appreciation indicates clearly to the respondent that the information is important to the survey sponsors.

12. Estimates of Annualized Burden Hours and Costs

The annualized estimates of respondent burden for each data collection form is provided below. An eligibility screener will be used to determine eligibility by assessing if respondent: 1) is 18 years or older; 2) injected drugs in the past 6 months OR used injectable drugs other than marijuana via non-injecting routes in the past 6 months; 3) is English speaking; 4) is able to give permission to participate in project; and 5) has not previously participated in this project (**Attachment 3**). Approximately 10,499 individuals will complete the eligibility screener. We estimate that it will take five minutes to complete the eligibility screener. Our target population is 300 participants per site or 1,800-9,000 for 6-30 sites. We anticipate that, on average, 16.66% or 300-1,499 persons (for 6-30 SSPs) will not be interested in completing a survey, yielding 2,100-10,499 eligible participants. We estimate that it will take 5 minutes to complete the project permission process and 30 minutes for the IDU survey.

The estimates in the table below cover the time that each respondent will spend communicating with the project staff to assess eligibility, review project permission form, and answer survey questions (if eligible).

Table A.12.1: Estimates of Annualized Burden Hours (Based on maximum number of participating SSPs (n=30)

Respondent	Form	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (hours)	Total Burden(in hours)
Persons Screened	Eligibility Screening Form (Att 3)	10,499	1	5/60	875
Persons who give permission	Model Project Permission Form (Att 6)	9000	1	5/60	750
Eligible Participants	IDU Survey (Att 7)	9000	1	30/60	4500
Total Annualized Burden					6125

B. Estimated Annualized Cost to Participants

Note: The hourly rate was determined by using data obtained from the U.S. Department of Labor, Bureau of Labor Statistics: http://www.bls.gov/cps/cpsaat39.htm

Table A-12-2: Annualized Cost to Respondents

Type of Respondent	No. of Participants	No. of Responses per Respondent	Total Burden Hours	Hourly wage rate	Total Respondent Cost
Persons Screened, (Att 3)	10,499	1	875	$22.15	$19,381
Persons who give permission(Att 6)	9000	1	750	$22.15	$16,612
Eligible Participants for IDU Survey, (Att 7)	9000	1	4500	$22.15	$99,675
Total Annualized Cost					$135,668

13. Estimates of Other Total Annual Cost Burden to Participants or Record Keepers

There are no other costs to participants associated with this proposed collection of information.

14. Annualized Cost to the Federal Government

The annualized cost to the government is $3,147,032. The cost of this project for the three years is estimated to be $9,441,096. The annualized cost is summarized in Exhibit 14.A.

Exhibit 14.A. NHBS Annualized Cost to the Federal Government

Expense Type	Expense Explanation				Annual Costs (dollars)
Direct Costs to the Federal Government	Personnel				$147,032
	Epidemiologist-14	1	15%	$17,637	
	Epidemiologist-13	1	15%	$14,925	
	Epidemiologist-13	1	75%	$81,000	
	Epidemiologist-12	2	15%	$12,551	
	Epidemiologist-12	1	25%	$20,919	
	Cooperative agreement funds				$3,000,000
	TOTAL COST TO THE GOVERNMENT				$3,147,032

*Salary estimates were obtained from the U.S. Office of Personnel Management salary scale at https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2018/general-schedule /.

The personnel related to the IDU-SP data collection include project officers (epidemiologists) at the GS-12, 13, and 14 levels, and a cooperative agreement. Travel is related to conducting site visits.

The information collection described in this request will be funded through cooperative agreements with state and local health departments through fiscal year 2021. CDC surveillance activities are routinely funded through cooperative agreements with state and local health departments.

Data for this project will be collected using REDCap a secure web-based data collection program (**Attachment 11**). Data entered by participants and staff will be transmitted directly to the secure REDCap server rather than stored locally on computers or tablets at each site. The award recipient will routinely download and clean the data files, and will provide biweekly recruitment monitoring reports to CDC. At the conclusion of data collection, the award recipient will process all data collected across the 6-30 participating sites and produce a clean, final data set for use by CDC. This dataset will be sent via a secure network to CDC.

The award recipient data analyst will have responsibility for analyzing the final data set. They will work with the award recipient and CDC epidemiologists to create data tables to be displayed in surveillance reports and other products.

Explanation for Program Changes or Adjustments

This is a new data/information collection.

15. Plans for Tabulation and Publication and Project Time Schedule

Data will be collected once from each site; clearance is requested for 3 years. The following is a brief overview of the IDU-SP Timeline. Data from 6-30 SSPs, will be collected in phases, 2-10 SSPs at a time.

Activities	**Time Schedule (Based on Expected OMB Approval: October 2020)**
Phase 1: (2-10 SSPs)	
Interviewer Training	4 months after OMB approval
Begin Data Collection	6 months after OMB approval
End Data Collection and Clean Data	9 months after OMB approval
Phase 2: (2-10) SSPs	
Interviewer Training	10 months after OMB approval
Begin Data Collection	12 months after OMB approval
End Data Collection and Clean Data	15 months after OMB approval
Phase 3: (2-10) SSPs	
Interviewer Training	16 months after OMB approval
Begin Data Collection	17 months after OMB approval
End Data Collection and Clean Data	20 months after OMB approval
Complete Analysis of Data	28 months after OMB approval
Publication of data	No more than 36 months after OMB approval

Data from IDU-SP will inform prevention programs services and increase existing knowledge in the behaviors about drug use and risk. See **Attachment 12** for sample analysis tables.

Most of the results are expected to be useful at the local level, while other results will be more meaningful aggregated across sites. The funded recipient has primary responsibility for the release of local data. CDC has primary responsibility for the release of data aggregated from all participating SSPs. These data are distributed to the participating agencies, researchers, policy makers and other interested parties through presentations

at local, national and international conferences, publications in peer reviewed journals, and presentations at different forums such as continuing medical education courses and seminars. Furthermore, CDC will regularly publish an IDU surveillance report using data collected annually. Depending on publication schedules, these reports will be published within 12 months - 18 months of the end of data collection.

Community members will be informed of IDU-SP findings through multiple conduits of information. National data results will be released through national publications and presentations at conferences. Local data results will be reported back to the community through means such as local publications, Epidemiologic Profile reports, and presentations to local SSPs and at local conferences and workshops.

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

The display of the OMB expiration date is not inappropriate.

17. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

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