Injection Drug Use Surveillance Project

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Supporting Statement B

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Justification_

The primary purpose of the Injection Drug Use 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. 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 this project 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.

1. Respondent Universe and Sampling Methods

The IDU-SP project has a two-stage sampling strategy. 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) US 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 US maintained by the North American Syringe Exchange Network (NASEN; https://nasen.org). SSPs will be excluded from the selection process if they are in metropolitan statistical areas (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 peers who use drugs will be recruited through a combination of direct recruitment at the SSP and peer-driven recruitment. At each of the 6-30 selected SSPs, 50 persons who are clients of the SSP will be recruited and invited to participate in the IDU-SP project. Recruitment at the SSP will continue until at least 50 persons who use SSP services and meet the project eligibility criteria are included in the total sample. The IDU-SP project eligibility criteria are as follows:

1)18 years or older;
2)injected drugs in the past 6 months OR used injectable drugs via non-injecting routes in the past 6 months;
3)able to give permission to participate in the project;
4)can complete the survey in English; and
5)had not previously participated in this survey.

Persons who complete the survey will be asked to recruit others they know who use drugs (other than marijuana) via injecting or non-injecting routes. This peer-driven strategy for recruitment is similar to respondent-driven sampling (RDS)(1). As in RDS, participants will be given up to 5 coupons to recruit their peers. 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. 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 total 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

Participants will be ineligible for participation if they:

- Are younger than 18 years of age;
- Are unable to speak or understand English;
- Had not injected or used drugs in the past 6 months;
- Do not have the capacity to give permission to participate in project;
- If they have already participated in the survey.

Selection of Respondents and Sample Size

The methods for the IDU-SP were adapted from the National HIV Behavioral Surveillance (NHBS), IDU cycles (OMB # 0920-0770; Expiration 01/31/2023)and in consultation with experts at CDC, NIDA and SAMHSA, who included sampling methodologists, those with expertise conducting research or behavioral surveillance activities with persons who attend SSPs and use drugs, and public health practitioners who

provide services to these populations in rural and urban areas. Sampling methods to recruit participants and drug-using peers is complicated by the fact that these populations are marginalized and hidden due to the illegal or illicit behavior of their members. As such, SSP clients and their peers who use drugs will be recruited via a combination of systematic sampling at selected SSPs (i.e., every nth person using SSP services) and peer-driven recruitment. Recruitment at SSPs will benefit from the strong, trusted relationship these programs build with this population that will aid in achieving a high participation rate. Using this recruitment approach in combination with the peer-driven approach, will allow these initial participants to recruit their peers into the project. Peer-driven approaches, like RDS, have been successful in reaching deeper into the networks of hidden, hard-to-reach populations, including people who use drugs. Using the combination of SSP and peer-driven recruitment will allow for a standardized approach to achieving the target sample size of participants at each SSP (n=300).

2. Procedures for the Collection of Information

All IDU-SP project data are anonymous; no direct identifiers will be linked to any data (e.g., name, address). The main data collection components include the eligibility screener, behavioral survey, and specimen collection for HIV and HCV testing, which will all be conducted by trained project staff. Participation in the project is voluntary. Respondents may refuse to participate at all or in part of the survey. Respondents may refuse to answer questions or stop participation at any time without penalty. Each participating SSP will obtain approval for this project from any relevant Institutional Review Board (IRB) as required by their local review and approval processes and federal regulations before data collection.

Persons who are eligible for the IDU-SP will complete a project permission form, whereby the interviewer will read the form and indicate on the project portable computer whether the person being recruited provided verbal permission. Signatures could be identifying and therefore will not be collected during the project permission process for this anonymous survey. Participating project areas will therefore be asked to obtain a waiver of signed form per their IRB or other local regulations.

After permission is given, a 30-minute behavioral survey will be conducted using the Research Electronic Data Capture (REDCap) software on a portable computer. REDCap is a secure web-based application that allows interviewer-administered and an optional self-administered

survey data collection. The self-administered component has an audio-recording feature that allows potentially sensitive questions (e.g., drug use, sex practices) to be read out loud using headphones so that participants can answer questions privately. The audio-recording option is provided to assist participants who may have difficulty reading. Participant can opt out of this option and continue the interview with the interviewer administering the survey questions.

In addition to the behavioral survey, participants will be offered anonymous HIV and HCV testing, which they may refuse with no effect on participation in the survey. Those who give 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. Participants who screen positive for HIV and 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.

Participants will be given approximately $20 for participation in the quantitative survey, $10 for taking voluntary HIV and HCV tests, and $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 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 surveys. A token is also provided to persons who participate in CDC’s HIV-related data collections among other populations, 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).

After a brief training on the recruitment process, those who agree to

recruit their peers will be given up to 5 coded, non-replicable coupons. The participant will be told to give one coupon each to 1 to 5 peers (determined locally) meeting the eligibility criteria, based on the recruitment training script. Each coupon has the local project name and location(s) printed on it with a brief description of the project. The code on the coupon is linked to 1) the Survey ID of the participant the coupon is issued to (i.e., the recruiter) and 2) the Survey ID of the participant returning the coupon (i.e., the recruit). The coupon information is entered and stored in the recruitment coupon spreadsheet. After receiving coupons and recruiter training, the participant is provided the token of appreciation for participating in the survey and HIV and HCV testing (as applicable) and given instructions about returning for the token of appreciation for recruiting others. Participants will be given $10 for each peer recruited (up to 5) into the IDU-SP.

Quality Control

Data quality will be ensured through project staff training, close monitoring of all operations and data collection, and site visits. Data will be collected electronically using the REDCap software; no paper instruments will be used to collect data for the IDU-SP. The REDCap survey instrument will include an interviewer-administered component on key background and service access information and a self-administered component that will allow participants to answer potential sensitive questions (e.g., drug use) in private, thus improving validity of the responses. The REDCap technology will improve data quality in several ways:

a) Interviewer errors are reduced because interviewers do not have to follow complex routing instructions; the computer does the routing for them.
b) Respondent errors are also reduced. Consistency checks are programmed into the survey so that inconsistent answers or out-of-range values can be corrected or explained while the survey is in progress.
c) Use of REDCap also reduces coding and coding errors, which makes it possible to prepare the data for analysis faster and with fewer errors.

A multi-day interviewer training will occur before the start of data collection. This training will cover general interviewing skills, sampling and recruitment protocols, and a question-by-question review of the survey to ensure interviewers understand the purpose of each question and how it should be read and coded in the portable computer. Interviewers will be required to practice administering the survey during the training. The training is also meant to address interviewer integrity, underscoring the importance of collecting quality data and

the consequences of inappropriate behaviors, including falsification of data. Project staff will also be trained on how to conduct recruitment procedures, such as approaching SSP clients and providing effective recruiter training on how to recruit their peers.

During the data collection period, interviewers will be monitored by the field supervisors or other management staff. Surveys/interviews will be monitored based on a locally-determined evaluation schedule. Feedback will be provided for areas of improvement and in cases of incorrect implementation of the protocol. Monitoring peer-driven recruitment will also allow for feedback on ways to help improve response rates.

CDC will conduct at least one site visit per cycle. The purpose of the site visit will be to monitor adherence to the IDU-SP protocol, observe recruitment and survey implementation, and obtain feedback on project procedures.

Data entered into REDCap are transmitted directly to a secure, cloud-based server. The award recipient will conduct frequent data quality checks and make adjustments as needed. The survey will include built-in logic checks for key variables. At the conclusion of data collection, the award recipient will clean the full dataset and send a finalized database to CDC. Individual SSPs will also be provided with a final dataset with data collected from their local program.

The survey instrument will not collect direct identifiers (e.g., name, address, social security number).

3. Methods to Maximize Response Rates and Minimize Non-response

Peer-driven recruitment is adapted from RDS, a sampling methodology developed to recruit hidden, highly stigmatized populations, including people who use or inject drugs. Previous studies using RDS find that one-half to two-thirds of persons recruited by their peers for the project will present for eligibility screening (1-7). We expect that 90% of participants who will be screened for participation in the IDU-SP will be eligible to take the survey. This is within the range of those achieved in other studies using similar sampling methods (6,8,9). In addition, response rates among those found eligible are generally high because those who have taken the initiative to come to the field office to be screened for the survey are motivated to participate. Generally, persons who are eligible and not interested in participating in the survey will not make the effort to come to the field office with the coupon.

Response rates will be monitored through conference calls on a bi-weekly basis, offering the opportunity to share strategies for improving response rates. Recruitment statistics and sample demographics will also be reported to CDC on a bi-weekly basis to monitor sample distribution. In addition, research indicates that providing a token of appreciation to respondents helps raise response rates for long, sensitive, in-person surveys (10). A token is also provided to persons who participate in CDC's HIV-related data collections among other populations, 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).

Convenient hours of operation for participating SSPs may also maximize response rates. Prior to conducting the IDU-SP, the field staff in each participating area will review any existing accessible data sources to determine the characteristics (e.g., race, ethnicity, age, geographic location) of SSP clients and their peers. The field staff will also obtain input on the logistics of data collection from local stakeholders and members of the local community of persons who inject or use drugs. This input will help the local staff identify the most appropriate hours of operation for the field sites and avoid barriers to participation. In order to reduce disruption of SSP services, the survey will be conducted in a private room or an area away from other SSP clients.

When a peer recruiter initiates contact with project staff, such as when a peer recruiter returns to the field site for tokens or other services, the field staff will remind recruiters to encourage any recruits who have not yet presented for eligibility screening to do so.

4. Tests of Procedures or Methods to be Undertaken

The data collection instrument was developed using questions from previous CDC surveillance projects, such as the NHBS IDU Cycle (OMB # 0920-0770; Expiration 01/31/2023)and the Survey and Rapid Testing project (BART) (OMB No. 0920-0883, exp. 4/30/2014), and reviewed by experts at CDC, NIDA and SAMHSA. This survey will focus on methods

that are feasible and practical, while ensuring that the methods and approach are scientifically sound. Prior to implementation in the field, project staff will test the skip patterns and responses of the data collection instruments to ensure a streamlined data collection instrument that produces valid and reliable data.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Individual Consultants on Statistical Aspects

The following individuals consulted on statistical aspects only. They are not involved in collecting or analyzing the data.

Teresa Finlayson, PhD
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Individuals Collecting and/or Analyzing Data

Project staff at individual SSPs will be responsible for data collection. These SSPs and staff have not yet been identified.

Staff at the University of Washington (UW), the award recipient, will be responsible for leading the implementation of the survey with SSPs, monitoring data collection, managing incoming data, and analyzing the data.

UW Project Staff
Staff can be reached at the following address:

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CDC is not directly engaged with human subjects during data collection. However, CDC project staff below will monitor progress of the project.

CDC Project Staff

All CDC project staff can be reached at the following address and phone number:

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