OMB #0920-new

Prevent Hepatitis Transmission among Persons Who Inject Drugs H-Tips

Section B: Supporting Statement

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Statistical Methods

Description of statistical methods based on the Study Protocol and Data Collection Instrument.

1. Respondent Universe/Sampling Methods

Reduce Hepatitis Infections by Treatment and Integrated Prevention Services (Hepatitis-TIPS) among Non-urban Young Persons Who Inject Drugs recruits a convenience sample of young persons who inject drug (PWID) using multiple recruitment approaches. Young adult PWID will be recruited directly and in-person; study invitation cards and flyers will also be used at recruitment locations, with community providers and by word of mouth. Study participants will also be asked to recruit their peers. The respondents are selected from venues that serve PWIDs including harm reduction programs. We anticipate to recruit a total of 995 young PWID from two sites, of whom 895 will be enrolled for the survey. The sample size was calculated with an estimated 40% prevalence of HCV infection. This sample size will provide 80% power with alpha=0.05 to detect effect sizes of 0.13 or greater and a minimum OR of 1.77 if the prevalence of the risk exposure of interest (P_0)=0.50.

Respondents are selected using convenience sampling and thus will not be representative of the national PWID population. However, if the anticipated number of participants could be recruited data could be applicable to the young adult PWID non-urban population in the selected area as information in this population is lacking. Information collection activities will target a specific population that meets the following inclusion criteria:

Subjects. Young adult PWID age 18-30 years.

Inclusion criteria: Understand spoken English or Spanish; able to provide informed consent; provide contact information including: name, 'street name' or nickname; and address, email, or phone number of a housed friend or relative who would know their whereabouts.

- Age 30 years or younger; history of injection drug use in the past 12 months;

Exclusion criteria: Over age 30; planning to leave or travel outside the region in the next 3 months; intoxicated or otherwise impaired to undergo informed consent or to complete a 60-minute questionnaire.

Information collected for this study is not generalizable to the PWID population in the geographic study of the projects or to the general PWID population.

2. Procedures for the Collection of Information

A structured training of local field staff will occur prior to implementation of data collection. This training will cover general interviewing skills, the sampling and recruitment protocol, 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 computer. Interviewers will have opportunities to practice administering the eligibility screener as well as going through the computer-assisted interview. The training will also address interviewer integrity, underscoring the importance of collecting quality data and the consequences of inappropriate behaviors, including falsification of data.

After eligible young persons who inject drug have been identified using the screener survey informed consent will be solicited. Those who consent to participate will be provided appropriate reimbursement for their time and travel costs. TIPS collects survey data through a computer-loaded questionnaire. The complexity of the instrument—with skip patterns and logic checks—and the sensitivity of some of the survey questions necessitate a computer-assisted interview. However, the survey questionnaire will be administered by an interviewer. Using an interviewer to administer the eligibility screener will allow time for TIPS staff to establish rapport with the respondent and to assign a unique ID for the survey.

Data quality is ensured by use of computer-assisted interviewing, interviewer training and monitoring, site visits, and data editing. Computer-assisted interviewing improves data quality in several ways: Interviewer errors are reduced because interviewers do not have to follow complex routing instructions; the computer does it for them. Respondent errors are also reduced. Consistency checks are programmed into the questionnaire so that inconsistent answers or out of range values can be corrected or explained

while the interview is in progress. Finally, use of computer-assisted interviewing also reduces coding and coding errors, which makes it possible to prepare the data for analysis faster and more accurately.

If, during the process of interviewing and data collection, the study team becomes aware of the need for treatment of any participant, referrals shall be made to appropriate medical care providers. Arrangements will be completed for respondents to receive free hepatitis A and B vaccinations if they are eligible for vaccination. Referrals will also be offered for medical treatment and follow up of viral hepatitis and HIV infection if blood test results indicate the results to be positive. The referral will be made after appropriate posttest counseling. Study coordinators and interviewers will be trained regarding issues that commonly arise when working with PWIDs including participants high on drugs.

Young injection drug users that were recruited using any of the recruitment venues/methods can decline to participate in the project. Those who decline to participate in the project will be informed about locally available support for injection drug users and will also be referred for free vaccination against hepatitis A and B virus.

3. Methods to Maximize Response Rates and Deal with Nonresponse

- Thorough explanation of the study visit schedule and procedural requirements during the informed consent process, and re-emphasis at each study visit.
- Compilation of detailed contact tracing and locator information at the study screening visits including phone and SMS (texting) numbers, locations where they may be found, and people who may be contacted to help locate them (eg., friends, family). The information will be actively reviewed and updated at study check-ins and follow-up visits.
- Use of appropriate and timely visit reminder mechanisms (e.g., Facebook, telephone and e-mail).
- Immediate and multi-targeted follow-up on missed visits.
- Use of trained outreach workers to complete in-person contact with participants at community locations, homes, venues, etc.
- Regular communication with the service and community based

organizations to increase awareness of the purpose of HCV prevention research and the importance of completing research study visits. The study team will generate weekly reports on the number and percentage of participants completing the follow-up visits throughout the course of the study. Study investigators and outreach staff will track retention rates closely and work with the study site as needed to take any required action to address below-target retention rates.

- All eligible respondents will be compensated for their time and cost of travel. All other participants will be reimbursed for their time and cost of travel. All participants will also be tested for HCV, HBV and HIV infection and will be offered vaccination against hepatitis A and B. Participants with evidence of HCV infection will be referred for care and treatment. Participants will also be referred for other services including substance abuse treatment. These procedures are expected to increase response rates among the participants.

4. Tests of Procedures or Methods to be Under Taken

The majority of questions for this project were developed using questions from previous studies conducted in PWID. Screening of respondents for antibody to hepatitis C virus (anti-HCV) by enzyme immunoassay (EIA) and RNA test on sample collected from eligible participants will be carried out at qualified laboratory selected by the grantee. Participants will also be offered testing for the presence of co-infection with hepatitis B virus and human immunodeficiency virus. A trained qualified phlebotomist will collect two serologic samples of at least 5.0ml each from consenting eligible participants. The consent forms for specimen collection (attachment 3) will clearly detail the adverse events associated with blood draw. It is known that major adverse events related to drawing blood are extremely rare. Study participants will be referred to prevention services and care and treatment. They will also be asked to return every 3 months for follow up interviews and HCV blood test.

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

Senior staff of the Division of Viral Hepatitis was consulted about the statistical aspects of the project, including the

sampling strategy, analytic methods for examining the objectives, and sample size. Data will be collected by staff of University of New Mexico and University of Cincinnati. The following individuals have been consulted on the statistical aspects.

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