

# **Prevent Hepatitis Transmission among Persons Who Inject Drugs**

**OMB #0920-new**

## **Section A: Supporting Statement**

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## **Prevent Hepatitis Transmission among Persons Who Inject Drugs**

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- **Goal of the study:** The overarching goal of this project is to use epidemiologic data on risk behaviors, drug use patterns, and injection networks to support the development and implementation of an integrated approach to provide screening, diagnosis, care, treatment, and prevention of HCV infection among young non-urban PWID.
- **Use of collected data:** Data will be used to improve our understanding of HCV infection in non-urban PWID and determine the risk factors, barriers, and willingness to access HCV care and treatment services and immediate and long term outcomes of treatment. The project will also provide linkages to appropriate prevention services.

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47. **A. Justification**

48. **A.1 Circumstances Making the Collection of Information Necessary**

49. The Centers

for Disease Control and Prevention, Division of Viral Hepatitis (DVH) requests new approval for 3 years of this information collection request (ICR) entitled, "Prevent Hepatitis Transmission among Persons Who Inject Drugs". This project will collect information including history of illicit

drug use and associated risk behaviors, access to viral hepatitis and HIV testing and care, and acceptance of vaccination, drug treatment, and other services among young persons who inject drugs (PWID) in rural and suburban settings. Such information from young PWID is lacking. Therefore, the collection of this information will help to increase our understanding of how to treat and prevent the spread of HCV among young PWID.

50. Background

51. The rates of HCV infection are highest among illicit-drug users, particularly persons who inject drugs (PWID). The Centers for Disease Control and Prevention (CDC) continues to monitor the national incidence of acute viral hepatitis through passive surveillance of acute cases confirmed by laboratory test. In 2013, 61% of acute hepatitis C cases identified injection drug use as a potential risk factor for HCV infection. PWID have barriers to healthcare access and use and face stigma associated with injection drug use.

52. Through enhanced surveillance and epidemiologic investigations focusing on PWID aged 30 years and under, the CDC is aware of an ongoing epidemic of HCV infection fueled by injection drug use, especially among those living in non-urban areas. The term non-urban, for the purposes of this information collection request (ICR), is defined according to the National Center for Health Statistics Urban-Rural Classification Scheme<sup>1</sup> as meaning "outside of urban core counties of a large metropolitan area".

53. Despite two decades of declining incidence, the number of new HCV infections in the United States reported to the CDC increased by nearly 150% between 2010 and 2013 <http://www.cdc.gov/hepatitis/Statistics/2013Surveillance/index.htm> and data from several states suggest this increase is related to injection drug use among young adults in rural and suburban areas. Early abuse of prescription opioids is a commonly reported problem leading to heroin injection. Over the past decade CDC, State and local health departments have identified focal outbreaks of HCV infection among young PWID in non-urban areas.

54. The overarching goal of this project is to use epidemiologic data on risk behaviors, drug use patterns, and injection networks to support the development and implementation of an integrated approach to provide

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<sup>1</sup> NCHS Urban-Rural Classification Scheme for Counties NCHS Urban-Rural Classification Scheme for Counties: [http://www.cdc.gov/nchs/data\\_access/urban\\_rural.html](http://www.cdc.gov/nchs/data_access/urban_rural.html)

screening, diagnosis, care, treatment, and prevention of HCV infection among young non-urban PWID.

55. This research will improve our understanding of HCV infection in non-urban PWID and determine the risk factors, barriers, and willingness to access HCV care and treatment services. This project will provide linkages to appropriate prevention services, including access to clinical interventions, harm reduction strategies, drug treatment interventions, and treatment of HCV, HBV, and HIV infection, when warranted.
56. This request is authorized by Title III - General Powers and Duties of the Public Health Service, Section 301 (241.)a. Research and investigations generally (**Attachment 1**).
57. Overview of the data collection system
58. The Prevent Hepatitis Transmission among Persons Who Inject drugs will recruit participants into the study and will collect data through a face-to-face interview. Data is collected from a prospective longitudinal cohort of participants using an initial and follow up survey. A computer-based interview instrument will be deployed and accessed from a tablet. For each person recruited, a short screening survey will be administered by an interviewer to assess various eligibility criteria and limited demographics. If eligible for the survey a consent form is provided and the respondent will continue the interview with the interviewer. All consenting participants will be offered blood test for viral hepatitis and HIV at the initial and follow up visits. The transmission of these data (de-linked and de-identified) is explained in A.10.
59. Items of Information to be collected
60. The survey is designed to collect data that will enable the CDC to better understand the risk factors for HCV infection. The participants in the survey will be recruited from venues serving PWID including syringe and needle programs and substance abuse treatment programs. Recruitment will take place at approximately 6 to 8 weeks after obtaining OMB approval. Information collection will be conducted in a designated study van or location at or near the recruitment site.
61. Information collected in the eligibility screener and initial and follow up behavioral questionnaire (**Attachment 3A, 3B, 3C**) will include self-reported demographics, the number of young IDUs the respondent is acquainted with (or

network size), and sexual and substance use behaviors. We will also collect demographic data, risk factors for HCV infection, missed opportunities for prevention, access to medical care, access to mental health, knowledge about HCV status and HCV testing. Data collected through this study are stored and accessed by a survey identification number at the study site. Other data collected through this study, while sensitive, are not personally identifiable. This information includes drug use which is associated with HCV infection, hepatitis diagnosis and testing, history of incarceration, alcohol use, and access to care.

**62. 2. Purpose and Use of Information Collection**

63. The purpose of information collection is to conduct an epidemiological investigation of risk factors associated with HCV infection in young ( $\leq 30$  years) persons who inject drugs (PWID) in non-urban areas. Findings will further inform strategic planning and program improvement; inform recommendations and strategies of increasing early identification of infected PWID and linkage to care, based on participant characteristics; identify risk behaviors and drug use patterns to be able to target treatment and prevention strategies for reducing HCV transmission and reduce or address disease burden among the infected population; produce specialized reports that will inform grantees, CDC Project Officers, HHS, Congress and other stakeholders of the process, outcome and accountability measures associated with the cascade of care of PWID; assess public health prevention funds and resource allocation with respect to the prioritized at-risk population; and advocate the needs for priority setting and budget allocation for hepatitis prevention.

**64. 3. Use of Improved Information Technology and Burden Reduction**

65. Responses will be directly entered in a secure laptop computer minimizing the burden to respondents and interviewers. The interview instrument will be developed using survey software. Administering the survey using a computer generated questionnaire will reduce the length of interview by correct application of skip patterns.

**66. 4. Efforts to Identify Duplication and Use of Similar Information**

67. A review of currently-funded programs did not identify potential areas of duplication. No known department or agency has carried out studies similar in scope to Prevent Hepatitis

Transmission among Persons Who Inject Drugs. Program reviews were conducted to identify potential areas of duplication; however, none were found to exist. The CDC also performed an extensive literature search for similar methodological studies and found no similar studies.

68. Within the CDC, we explored the following data collection systems and incorporated several elements from other surveys into the attached survey. The following CDC-sponsored surveillance systems were evaluated for duplication and use for the proposed project:

- Study to Assess Hepatitis Risk (STHR) (OMB #0920-0804 expired in 2012)
- National HIV Behavioral Surveillance (NHBS) (OMB 0920-0770 expires 3/31/2017)

69. None of these projects had information that could provide information from young PWIDs to understand the epidemiology of HCV infection among non-urban PWIDs. CDC has verified that there are no other collections that duplicate the data collection tools and methods included in this request.

**70. 5. Impact on Small Business or Other Small Entities**

71. No small businesses will be involved in this data collection.

**72. 6. Consequences of Collecting the Information Less Frequently**

73. The activities involve a baseline and follow up (up to 4 times) collection of data. Less frequent collection of data will not allow us to understand the uptake of integrated prevention services to include but not limited to testing, vaccination for Hepatitis A and B, and linkage to care, outcome of treatment provided as part of this project and its impacts. Repeated follow up will allow us to determine risk factors associated with re-infection after completion of HCV treatment.

**74. 7. Special Circumstances relating to the Guidelines of 5 CFR 1320.5**

75. The request fully complies with the guidelines of 5 CFR 1320.5.

**76. 8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency**

77. The 60-day federal register notice to solicit public comments was published in the Federal Register on June 30, 2015, pages 37264-37265, Vol. 80, No. 125 (**Attachment 2**). One public comment was received (Attachment 2A) and response (Attachment 2B) was provided.

78. Senior staff of the Division of Viral Hepatitis were consulted about the statistical aspects of the project, including the sampling strategy, analytic methods for examining the objectives, and sample size. No outside consultations were involved in the project. Data will be collected by staff of University of New Mexico and University of Cincinnati.

**79. 9. Explanation of Any Payment or Gift to Respondents**

80. Persons who are eligible to participate in this interview will be offered tokens of appreciation for participation or completion of the initial survey, follow up surveys, and participation in testing and referral. This study aims to obtain information to be used in similar population in other locations in the future. Thus the study aims to maximize the participation rate to have the highest quality of data and be able to conclude that findings are not biased by poor participation. A participant will receive \$25 each for completing the initial survey and HCV infection education session, \$10 for follow up visits with survey (maximum of 4), \$5 for visits for laboratory results and HCV infection treatment follow up (maximum of 5). Additional incentives may be provided to those who recruit an eligible participant who completes the survey (the "recruiter reward"). Recruiter rewards will be approximately \$10 for each referral for a maximum of three peer referrals which is standard for respondent driven sampling (RDS) studies. Use of incentives has been found to effectively improve participation of hard-to-reach and highly selective populations when posing highly sensitive questions.

81. The need for and the amount of incentives proposed in this ICR is based, in part, on the fact that other, similar research projects among populations at increased risk for HIV infection offer similar incentives. Thus, without incentives, it is likely that participation would be low. Incentives were used in other similar surveys: CIDUS I (OMB, exp. 06/30/2004); MMP (OMB-0920-0740, exp. 06/30/2010); NIC (OMB 0920-0748, exp. 08/31/2010); STAHR (OMB); and NHBS (OMB 0920-0770, exp. 03/31/2011). Each of these projects collected information from PWIDs and non-IDU populations.



**82. 10. Assurance of Confidentiality Provided to Respondents**

83. Each participant will be assigned a unique identification number which will be recorded both on paper and electronically. The unique IDs will be used to link information obtained from the surveys, laboratory results, and prevention services of the participants. The link will be deleted prior to transmitting any data to CDC. The CDC will only receive data with no identifiers.
84. Documents containing personal identifying information (PII) including consent forms, laboratory, and vaccination tracking forms will be kept by the University of Cincinnati and University of New Mexico, in locked file cabinets and on password protected computers. Only project staff will have access to this information in order to identify participants for post-test counseling and referral for vaccination and hepatitis and HIV medical services as appropriate. All de-identified data will be maintained in a dataset on-site for a minimum of five years after study completion.
85. The National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention has determined this project to be research, however, CDC is not engaged (**Attachment 5C**). CDC is funding this study under a cooperative agreement. CDC's role is to provide technical support and has no involvement or interaction with study participants. The grantees have submitted the protocol (**Attachment 4A, 4B**) to their respective IRBs and obtained approvals (**Attachment 5A, 5B**). Both grantees have obtained certificate of confidentiality for this study (Attachment 5D, 5E).
86. Interviewers and data managers will undergo security and confidentiality training to reinforce the importance of keeping the data secure and private. A number of required protections ensure the security of the data on laptop computers. The laptop computers are used solely for data collection activities specifically to this project only and data are encrypted when stored on a laptop computer. Laptop computers are protected by using a coded password only known by authorized project staff. The laptop 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 interview each day. When not in use in the field, the laptop computer will be locked in a drawer or office. Grantees will transmit data to CDC through a 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). No identifying information of any participant will be transmitted to CDC.

87. The computer on which the list sits will not be internet enabled. When not in use, the computer on which the list sits will be locked in a secure place and will use full disk encryption protection. The list of encrypted information will be destroyed immediately upon the conclusion of data collection. The hard drive on which the list was written will be overwritten on study completion. The list of names and unique identification numbers will be destroyed at the conclusion of data collection at each site and will never be linked to data.
88. The protocol and consent form has been reviewed and approved. The informed consent process for respondents will be fulfilled by (1) obtaining a consent document signed by the respondent or (2) by having the interviewer sign a consent document attesting to the respondents' verbal consent. The consent form is included as **Attachment 6A and 6B**.
89. Respondents will be informed that their data will be treated in a secure manner and will not be disclosed, unless otherwise compelled by law. The confidentiality language of the consent form also explains to the respondent that no one except study staff at the specific participating site and CDC will have access to the survey data and further that CDC will have no information to link the survey data to any participant. The interview will be conducted by trained staff in a private location where the questions and responses cannot be overheard by others. All consent forms will be stored in a secure location, separately from other information collected from participants.
90. The consent form also informs the respondent that participation in the survey is voluntary. Most of the questions allow the respondent the option of refusing to provide a response. Respondents who opt out of the survey will not be considered eligible to participate in the collection of blood specimens.
91. **A.10.1 Privacy Impact Assessment**
92. The CDC NCHHSTP Coordinator has determined that the Privacy Act does not apply to this information collection.

CDC will not receive any personally identifiable information (PII), and no data will be linked to any PII collected. PII will only be used to develop a unique identification number to ensure that an individual has not participated previously and to link data collected during follow up investigation. This list of names will be destroyed at the conclusion of data collection at each site. When data are sent to CDC for review, no PII will be linked to or included in the database. Data collected through this project are stored and accessed by a survey identification number so that personal identifying elements will remain inaccessible to human operators of the computer except at data entry.

93. The safe guards described above will protect the security and privacy of the data. In addition, these safeguards are in place at the study sites to prevent breaches of privacy. Name and other locator information will be used to contact consenting participants in order to inform them about the results of HCV testing and will be held temporarily and only at the local level by the grantees. This information will not be provided to CDC.

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

95. The survey contains questions that may be perceived as sensitive in nature. Questions about injection drug use are needed to assess HCV risks and testing for hepatitis C is needed to assess HCV prevention, testing and treatment services and how these may relate to disclosure attitudes and behaviors. Furthermore, these questions are needed to gain information and insight that will be used to strengthen CDC's prevention efforts for those at-risk for hepatitis C. In no case will a participant's social security number be obtained by any staff.

96. The context in which questions are asked also help to overcome their potential sensitivity. There are several steps 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."
- Consent scripts make it clear that the survey is sponsored by CDC and the grantees and that the information will be put to important uses.
- Phone numbers are provided if the respondent has questions about the survey.

- The questionnaire is carefully organized to lead smoothly from one topic to another. Transitions are made clear to respondents and the need for the information explained. Assurances about the privacy and confidentiality of the data are reiterated.
- The payment of an incentive indicates clearly to the respondent that the information is important to the survey sponsors.

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**98. 12. Estimates of Annualized Burden Hours and Costs**

**99. 12. A. Estimates of Annualized Burden Hours and Costs**

100. The annualized response burden for this sub-collection is estimated to be 949 hours; details are provided in exhibit A.12.A. The only respondents in this study will be persons who inject drugs (PWID). All individuals participating in the study will be tested for viral hepatitis and HIV. Our goal is to enroll and follow up a total of 895 individuals across the two sites over 3 years period. In order to achieve 895 participants we will approach 995 recruits anticipating about a tenth of recruits may either be ineligible to participate or refuse to participate. The entire participation process will take a maximum of 70 minutes; 10 minutes for the screening and 60 minutes for the initial questionnaires. Each follow up interviews will take approximately 30 minutes.

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**103. Exhibit A.12.A. Estimate of Annualized Burden Hours**

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105. Type of Respondents	106. Form Name	107. Number of Respondents	108. Number of Responses per Respondent	109. Average Burden per Respondent (in hours)	110. Total Burden (in hours)

						hours)	
111. WID	P	112. Eligibility Screening - Questions	113. 32	3	114. 1	115. 10/60	116. 55
117. WID	P	118. Initial survey	119. 98	2	120. 1	121. 60/60	122. 298
123. WID	P	124. Follow up survey	125. 98	2	126. 4	127. 30/60	128. 596
129.	Total						130. 949

131.

**132. A.12.B. Estimated Annualized Burden Costs**

133. The annualized costs to the respondents are described in Exhibit A.12.B. The United States Department of Labor Statistics May, 2014.

[http://www.bls.gov/oes/current/oes\\_nat.htm#31-0000](http://www.bls.gov/oes/current/oes_nat.htm#31-0000) was used to estimate the hourly wage for the general public for the purpose of this generic request. The figure of roughly \$20.00 per hour was used as an estimate of average hourly wage for adults. Thus, the total anticipated annual cost to participants for collection of information in this project will be \$18,980.00.

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**Exhibit A.12.B: Estimated Annualized Burden Costs**

135. Type of Respondent	136. (Form Name)	137. Total Burden Hours	138. Hourly Wage Rate	139. Total Respondent Cost
140. Eligibility		141.	142. \$20	143. \$1

143. Screener - Questions and process	55	.00	,100.00
144. Initial survey	145. 298	146. \$20.00	147. \$5,960.00
148. Follow up survey	149. 596	150. \$20.00	151. \$1,920.00
152. Total	153. 949	154.	155. \$18,980.00

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**157.**

**158. 13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers**

159. There are no other costs to respondents or record keepers.

**160. 14. Annualized Cost to the Federal Government**

161. This activity will involve participation of one CDC project officer who will assist with project design, obtain IRB and OMB approvals, and provide project oversight. Travel expenses include two site visits.

**162. Exhibit A.14: Estimates of Annualized Cost to the Government**

163. Expense Type	164. Expense Explanation	165. Annual Costs (dollars)
167. Direct Costs to the Federal Government	168. CDC Project Officers	169. \$40,000.00
170.	171. CDC Travel for Site Visits (2 trips per year)	172. \$7,000.00
173.	<b>174. Subtotal, Direct Costs</b>	<b>175. \$47,000.00</b>
176. Cooperative Agreement or Contract Costs	177. Contract with 2 grantees	178. \$40,000.00
179.	<b>180. Subtotal, Cooperative Agreement or Contract Costs</b>	<b>181. \$40,000.00</b>
182.	<b>183. TOTAL COST TO THE</b>	<b>184. \$44</b>

	<b>GOVERNMENT</b>	<b>7,000.00</b>
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**186. 15. Explanation for Program Changes or Adjustments**

187. No program changes or adjustments requested. This is for a new data collection.

**188. 16. Plans for Tabulation and Publication and Project Time Schedule**

189. Data collection will be completed during the 36 months after OMB approval is granted. The findings from this survey will be published in peer review journals within one year of completion of data collection. Abstracts will be presented at national meetings upon completion of the project. Abstracts and peer reviewed papers will focus on risk factors for HCV infection, barriers against use of prevention services including vaccinations against hepatitis A and B, barriers to linkage to substance use treatment services and challenges accessing HCV treatment.

190.

**191. Exhibit A.16: Project Time Schedule**

192.		194.	
193.	Activity	195.	Time Schedule
196.	Recruit and Screen Clients	197.	1-24 months after OMB approval
198.	Provide rapid HCV tests	199.	1-36 months after OMB approval
200.	Conduct Surveys	201.	1-36 months after OMB approval
202.	Analyze the data	203.	1-42 months after OMB approval
204.	Write up and present data	205.	36-48 months after OMB approval

206.

**207. 17. Reason(s) Display of OMB Expiration Date is Inappropriate**

208. OMB Expiration Date will be displayed.

**209.**

**18. Exceptions to Certification for Paperwork Reduction Act Submissions**

**210.** There are no exceptions to the certification.

211.