Injection Behaviors among Young Persons in Rural/Suburban Settings

Generic Information Collection request under 0920-0840
Expiration 2/29/2016

Section A: Supporting Statement

March 21, 2014

CONTACT

Jon E. Zibbell, PhD
Centers for Disease Control and Prevention
Division of Viral Hepatitis
Prevention Branch
Phone: 404.718.8851
Fax: 404.718.8595
Email: jzibbell@cdc.gov

Formative Research to Assess Injection Behaviors among Young Persons Who Inject Drugs in Rural and Suburban Settings

Table of Contents

Supporting Statement

A. Justification

A.1 Circumstances Making the Collection of Information Necessary

This request is for an approval of a sub-collection under a generic approval (Formative Research and Tool Development, OMB #0920-0840, expiration 2/29/2016), for a data collection entitled, "Injection Behaviors among Young Persons in Rural/Suburban Settings". This formative project will collect information as part of a preliminary investigation into the behavioral factors associated with the exponential increase of new hepatitis C virus infections among young persons who inject (PWID) drugs and reside in rural and suburban settings. This emerging HCV epidemic is a public health emergency that requires preliminary research as a first step toward developing informed research questions that can inform and guide future studies.

Quite recently, a swell of new HCV infections has been occurring in rural and suburban regions of the country among young persons (< 30) who inject drugs. The Centers for Disease Control and Prevention (CDC), has reported increases in HCV cases among young persons in Massachusetts (CDC, 2011), Pennsylvania (CDC, 2011) Wisconsin (CDC, 2010), upstate New York (CDC, 2008) and recently there have been reports of similar increases in the Appalachia region of the US (Havens, 2013). Yet, the reasons for the increase among young persons are not well understood, making the development of evidence-based, HCV prevention interventions challenging and speculative by nature.

The Centers for Disease Control and Prevention proposes to conduct a formative research study that will collect vital information about the behavioral factors associated with the increase in new HCV cases among young persons who inject (PWID) drugs in rural and suburban settings. Collecting this information will aid the development of HCV prevention interventions for those seeking services in HCV/HIV testing settings.

The purpose of this formative study is to field test a secure web-based survey instrument meant to collect information on the injection practices which place young persons at risk for HCV infection. Two HCV testing sites are funded. Both are syringe service programs (SSPs) and both provide risk reduction and HCV/HIV testing services to young PWID. One SSP is in a suburban milieu and the other is located in a rural area. We anticipate that at least some respondents may not have permanent housing and may not consider Wisconsin their permanent state of residence.

Accordingly, we allow respondents to enter a different zip code than the zip codes of the two sites where recruitment and testing occurs. This will allow us to check if people who provide a zip code outside of the study area really meant to give that zip code.

The intent of this study is to discover associations between injection behaviors and HCV infection – not to determine causality. The preliminary data generated from this formative study will be used to expand our understanding of said associations to both develop explanatory theory and formulate research questions that are more informed and better able to support future research. In addition, the data will allow us to develop interventions to mitigate risk. We anticipate initiating data collection in late November, 2014. 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**).

A.1.2 Privacy Impact Assessment

NORC at the University of Chicago (NORC) field staff will recruit potential respondents based on their responses to four yes/no questions used to determine study eligibility: 1. Date of Birth (to confirm between ages 18-29); 2. whether they have injected drugs in the last 12 months; 3. they could complete a survey in English; and 4. if they have a photo ID with them (**Attachment 4**). After providing verbal consent (**Attachment 5**), the participant will supply field staff with the following information: First Name and Last Name, which will be encoded with a seed number into a unique identification number/participation code. This participation code will be created using the SHA-2 algorithm. This unique identification number/participation code will allow NORC field staff to assure that the participant has not participated in the study previously. The code is not linkable to study data, other than to establish the fact that the individual was eligible for participation. Survey data, the linked HCV rapid test results and facility information about the SSP will all be stored on NORC's main server files. Data are entered directly into NORC's servers via a secure web-enabled system.

Steps will be taken to ensure data is secured, with a CDC certificate of confidentiality (CoC) (**Attachment 7**) providing legal protection of data and personal identifiers. Rapid HCV test results and survey data will be stored on secure servers with secure password protected files or in a locked file cabinet in the Principal Investigator's (PI) locked office. Only the NORC PI and Project Director (PD) will have access to the password for the master data file. ID numbers will only be used to link

participants in the study to the collected data. A list linking ID numbers to names will be kept separately in a locked location in the PI's office. After data analysis is completed, the grantees will destroy all participant PII and data.

The Privacy Act does not apply to this information collection. CDC will not receive any PII, and no data will be linked to PII. PII will only be used to develop a unique identification number to ensure that an individual has not participated previously. 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.

A.1.3 Overview of the data collection system

NORC maintains a production-ready network of servers that ensure reliable and secure support for all research data and activities. This project will be supported by NORC's Virtual Private Network / Citrix structure which links researchers from remote locations throughout the United States. All NORC authorized network users are issued an encrypted, challenge-response user-id and password for signing onto the network. All data from this project will be stored directly on the server, which is supported by an uninterruptible power supply, resulting in zero downtime or data loss in the event of power outages. In the unlikely event that hardware is stolen, burned or destroyed at the study site, data will not be able to be viewed or abstracted from the hardware without full security clearance.

A.1.4 Items of Information to be collected

The survey is designed to collect data that will enable CDC to better understand the hypothesized drivers of HCV infection. The survey is to be administered in Milwaukee and Illinois and conducted at venues serving persons with a history of drug injecting. Recruitment will take place at said venues approximately 6 to 8 weeks after obtaining OMB approval.

Using the IDU study protocol (**Attachment 8**), study participants will be asked to:

1. The NORC field staff will ask interested individuals their permission to be asked four yes/no questions to determine study eligibility: 1. Date of Birth (to confirm between ages 18-29); 2. Whether they have injected drugs in the last 12 months; 3. Whether they could complete a survey in English; and 4. If they have a photo ID with them (**Attachment 4**).

2. For eligible participants (answer yes to all 4 eligibility questions listed in Step 1), the field staff will review the informed consent with the potential participant, answer any questions the potential participant has, and ask the potential participant to verbally consent to participate in the study. The field staff will check Yes/No on whether verbal consent has been obtained and the participant will check Yes/No on whether they agree to complete the survey and the HCV test.
3. After verbal consent (**Attachment 5**), the participant will supply field staff with the following identifying information: First Name and Last Name which will be encoded with a seed number into a unique identification number/participation code. This participation code will be created using the SHA-2 algorithm based on the respondents first and last name and the seed number. The purpose of the code is to keep individuals from participating in the study more than once. The code is not linkable to study data, other than to establish the fact that the individual was eligible for participation. The list will be destroyed at the conclusion of data collection at each site.
4. The NORC field staff will then administer the hepatitis C test using the OraQuick rapid test, which involves a finger stick to acquire blood sample. Results will are available in 20-40 minutes and will develop as the participant takes the survey in order to minimize the total amount of time required by said participant.
5. After the hepatitis C test has been administered, NORC field staff will have participants complete the IDU survey via NORC laptop, which will take approximately 45 minutes (**Attachment 2A and 2B**).
6. Upon completion of the survey, the participant will be notified that their hepatitis C result is available and will have the option to receive their test result.
7. Finally, the participant will receive their electronic check card (which will be loaded with $15) as a token of appreciation. They will also receive 3 coupons (and their coupon number) to distribute to 3 other drug using contacts for potential study enrollment (**Attachment 6**). The referred individuals can bring in the coupon or the coupon number to one of the recruitment/data collection locations. For each successfully referred individual (success = study completion), the referring participant will receive an

additional $10 per referred individual (up to 3 referrals), which will be loaded onto their electronic check card.

A.1.5 Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age

There will be no survey content directed at persons under the age of 13.

A.2. Purpose of Use of the Information Collection

The purpose of this project is to conduct formative research on the injection behaviors of young PWID and the correlation of said behaviors to HCV infection. The intent of the study is to discover associations between injection behaviors and HCV infection – not to determine causality. The data generated from the study will be used to better understand these correlations and to build explanatory theory to support research.

A.2.1 Qualitative interviewing for surveillance, research, and intervention methods and material development

There is no qualitative interviewing. All questions in the survey instrument are quantitative and will provide preliminary data to develop future research questions.

A.2.2 Cognitive interviewing for development of specific data collection instruments

The survey contains questions to ascertain respondent’s rational ability -- not cognition.

A.2.4 Usability testing of technology-based instruments and materials

A 45 minute web-based survey will be tested as a technology-based instrument (**See Attachment 2A and Attachment 2B**). The survey is quantitative and consists of five sections: injection equipment; social structure; injection competency; personal characteristics; drug history. Participants will access the survey via a laptop computer.

A.2.5 Field Testing of New Methodologies and Materials

The proposed collection is designed to field-test a web-based survey instrument meant to obtain data on injecting behaviors that place people at risk for HCV infection. The objective of the field

test is to evaluate the instrument's feasibility as a web-based survey and to ensure that the lexicon is accurate, relevant and understood by the participants.

A.3. Use of Improved Information Technology and Burden Reduction

The IDU survey is an electronic survey that respondents will complete online via laptop. Use of an electronic survey not only ensures data quality but decreases respondent burden with built-in skip logic.

A.4. Efforts to Identify Duplication and Use of Similar Information

CDC has verified that there are no other collections that duplicate the data collection tools and methods included in this request.

A.5. Impact on Small Business or Other Small Entities

No small businesses will be involved in this data collection. NORC will be in the only entity collecting data.

A.6. Consequences of Collecting the Information Less Frequently

The activities involve a one-time collection of data so frequency of data collection is not an issue.

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

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

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

For sub-collection requests under a generic approval, Federal Register Notices are not required. A Federal Register Notice for the generic clearance 0920-0840, exp. 02/29/2016 was published on 08/2/2012, Vol. 77, No. 149, pages 46094-46095. No comments were received.

A.9. Explanation of Any Payment or Gift to Respondents

Study subjects will be provided a $15 token of appreciation (via electronic check card loaded with $15) at the completion of the survey and after receipt of rapid HCV test. In addition, participants will be informed verbally and in writing (via consent form) that they may refer up to three individuals (**Attachment 6**)

to the study and will receive an additional $10 token of appreciation per referral, up to a total value of $30 (3 referrals). The token of appreciation for referrals will be electronically loaded onto the participants' electronic check card so the individual will not need to return to the study site to receive the token. Individuals will be informed that they may participate in the survey only once.

A.10. Assurance of Confidentiality Provided to Respondents

The Privacy Act does not apply to this data collection. Identifying information (First Name and Last Name) is only needed by our study to implement the RDS design. There will never be a need to link personally identifying information to survey responses or test results. Identifying information only need be collected and maintained to ensure that participants do not attempt to participate multiple times to take advantage of financial incentives. Because of this, encryption can be used to hide individual identities because the project has no need to recreate participant identities from the coded data. There are several ways in which identifying information collected by the project will be protected.

- This study has a Certificate of Confidentiality (CoC) from the CDC
- The project will create no link between the identifying information and the survey responses. At worst, should all systems fail, the identifying information could only be used to say that an individual was a participant in the study.
- Personal identifying information (first and last name) and a seed number will be encrypted using the SHA-2 algorithm developed by the US National Security Agency. SHA-2 is a 256-bit encryption key which offers the strongest form of data protection available to the general public.
- 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.

Additionally, NORC is ensuring security of communication and data through the following:

- **Security.** NORC's security program is compliant with the National Institute of Standards and Technology recommendations at NIST 800.53 and has active projects for the Department of Labor, the Federal Reserve, and the Bureau of the Census that require independent audits to confirm compliance. Recent audits have found that NORC systems meet or exceed standard security requirements.

- **Physical security/facilities.** NORC takes great care to enforce physical security measures specifically designed to ensure that access to confidential data is restricted to only those researchers who possess the need, as well as the authorization, to review such information.

- **Network data security**. NORC requires the use of internal network data storage services to store all project-related data files. Partitioned network storage will be provided for the data collected in this study to mitigate the potential for data loss due to an accident, computer equipment malfunction, or human error, as well as to administer access rights regarding privacy issues related to both legal and contractual obligations.

- **Encrypted data and communication**. All remote access to internal NORC computing resources requires two-factor authentication and encrypted channels. Only secure, encrypted file transfers are used when exchanging files over the Internet. All of NORC's laptop computers are provisioned with an automatic full disk encryption system to protect against loss of sensitive data should any of these machines be lost or stolen.

- **Access control / authentication**. Passwords must meet stringent requirements for length and complexity and must be changed on a regular basis.

- **Virus protection**. All NORC computer systems are protected from computer viruses by centrally managed anti-malware software and distribution of the latest security patches. NORC's network is further protected by tightly controlled firewalls and email filtering technology.
- **Project personnel security practices and procedures**. NORC conducts a pre-employment background investigation on each new or returning employee. All NORC employees must complete

a Commitment to Confidentiality form as a condition of employment. In addition, all staff members receive security training specific to the project to which they are assigned.

CDC will not receive any PII. When data are sent to CDC for review, there will be no PII included in the database.

Prior to participating in any part of the study, participants will be required to give informed consent. Verbal consent will be obtained for the interviews and focus groups (**Attachment 5**); therefore, no participant names or signatures will be on the consent form. Participants will be provided with copies of the verbal consent form.

A.11. Justification for Sensitive Questions

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.

A.12. Estimates of Annualized Burden Hours and Costs

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

The annualized response burden for this sub-collection is estimated to be 179 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 hepatitis C via rapid test. Our goal is to interview and test 200 individuals at each participating site for a total of 400 tested across the two sites. The entire participation process will take a maximum of 53 minutes with a total of 2 minutes for the eligibility screener; 5 minutes for the consent form; 1 minute for the blood spot to conduct the HCV test; and 45 minutes for the web-based survey. The HCV testing time ranges from 20 to 40 minutes. The study is designed to acquire and test blood immediately following determination of eligibility and informed consent. The respondent then takes the survey while the results are processing.

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

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Respondent (in hours)	Total Burden (in hours)
PWID	Eligibility Screener - Questions	1,600	2	2/60	53
PWID	Consent Form	400	1	5/60	33
PWID	Screening and HVC Testing and 45 minute web-based survey	400	1	46/60	308
Total					394

A.12.B. Estimated Annualized Burden Costs

The annualized costs to the respondents are described in Exhibit A.12.B. The United States Department of Labor Statistics May, 2013. (http://www.bls.gov/oes/current/oes_nat.htm) was used to estimate the hourly wage for the general public for the purpose of this generic request. The figure of roughly $22.00 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 $3,938.00.

Exhibit A.12.B: Estimated Annualized Burden Costs

Type of Respondent (Form Name)	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
PWID: Eligibility Screener – Process	53	$22.00	$1,166
PWID: Consent Form	33	$22.00	$726
PWID: Rapid HCV testing (Screening and 45 minute web-based survey)	308	$22.00	$6,776
Total	394		$8,668

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

There are no other costs to respondents or record keepers.

A. 14. Annualized Cost to the Federal Government

This activity will involve participation of one CDC project officer who will assist with project design, obtain IRB (**Attachment 3**) and OMB approvals, and provide project oversight. Travel expenses include two site visits.

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

Expense Type	Expense Explanation	Annual Costs (dollars)
Direct Costs to the Federal Government	CDC Project Officer (GS-13,0.15 FTE)	$6,638.00
	CDC Travel for Site Visits (2 trips)	$2,000.00
	Subtotal, Direct Costs	**$8,638.00**
Cooperative Agreement or Contract Costs	Contract with grantees.	$75,000.00
	Subtotal, Cooperative Agreement or Contract Costs	**$75,000.00**
	TOTAL COST TO THE GOVERNMENT	**$83,638.00**

A.15. Explanation for Program Changes or Adjustments

No program changes or adjustments requested. This is for a new sub-collection under a generic approval.

A.16. Plans for Tabulation and Publication and Project Time Schedule

Data collection will be completed during the 12 months after OMB approval is granted.

Exhibit A.16: Project Time Schedule

Activity	Time Schedule
Recruit and Screen Clients	1-12 months after OMB approval
Provide rapid HCV tests	1-12 months after OMB approval
Conduct Surveys	1-12 months after OMB approval

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

OMB Expiration Date will be displayed.

18. Exceptions to Certification for Paperwork Reduction Act (PRA) Submissions 5CFR 1320.3(h)(1)-(10)

There are no exceptions to the certification.