Study To Assess Hepatitis Risk (STAHR)

Supporting Statement A

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A. Justification

1. Circumstances Making the Collection of Information Necessary

Background

The Centers for Disease Control and Prevention (CDC) requests approval for a 2 year pilot project, titled the *Study To Assess Hepatitis Risk (STAHR)*, to estimate the incidence of hepatitis C virus (HCV) infection among young injection drug users by means of serial cross sectional seroprevalence surveys. This project will apply and test different methods to recruit young injection drug users (IDUs) in order to estimate the population-based incidence of HCV infection.

Currently the CDC monitors the national incidence of acute hepatitis C through passive surveillance of acute, symptomatic cases of laboratory confirmed hepatitis C which captures a small fraction of acutely infected people, i.e., those who have symptoms and receive medical attention and appropriate laboratory testing during the acute phase of the disease. Seventy percent of these cases are IDUs. Passive surveillance for hepatitis C has been largely ineffective in reaching IDUs who are the primary risk population for hepatitis C.

This pilot project will address gaps in knowledge regarding the effectiveness of various recruitment methods for identifying young IDUs and associated characteristics that increase the risk of infection with HCV. STAHR will evaluate different recruitment venues and strategies and test a behavioral questionnaire specifically designed for IDUs to determine the feasibility of these approaches for a nation-wide surveillance system. STAHR will also evaluate the utility of using HCV nucleic acid testing (NAT), antigen-antibody testing, and other testing modalities to identify sero-incident (window period) infections. Knowledge of factors associated with acquiring HCV infection is essential to guide the development of prevention and control strategies.

Collection of acute hepatitis C surveillance data is authorized under U.S. Code title 42 section 241(a) of the Public Health Service Act (Attachment 1).

Overview of the data collection system

The STAHR pilot will use Respondent Driven Sampling (RDS), street outreach recruitment, and venue-based sampling methods to recruit participants into the survey. STAHR will collect screener data through a face-to-face interview and behavioral assessment data using computer assisted self interview. In the RDS recruitment method persons will be recruited by peers for participation in STAHR. A computer-based interview instrument will be developed using Questionnaire Development System (QDS) software (NOVA Research Company, Bethesda, Maryland) and accessed from a lap-top computer (Attachment 4). The core questionnaire will be administered by means of an audio, computer-assisted self-interview (ACASI). For each person recruited, a short screening survey will be administered by an interviewer to assess various eligibility criteria and limited demographics (Attachment 3). This interview will be computer-

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assisted. If eligible for the survey and consent is provided, the respondent will continue the computer-assisted interview without the interviewer. The electronic data collected in these interviews will be maintained indefinitely at CDC. The transmission of these data (de-linked and de-identified) is explained in A.10.

Items of Information to be Collected

Information collected in the eligibility screener (Attachment 3) and behavioral questionnaire (Attachment 4) will include self-reported demographics, the number of young IDUs the respondent is acquainted with (or network size), and sexual and substance use behaviors. At the end of the interview, the respondent will return the laptop to the interviewer, who will then ask a few questions to assess understanding of the questionnaire items.

STAHR will collect demographic data, risk factors for HCV infection, missed opportunities for prevention (including hepatitis A and B vaccination), access to medical care, and knowledge, attitudes, and beliefs about HCV infection. STAHR is anonymous and neither name nor social security number is collected. The date of birth will be used to link survey information to laboratory and vaccination information. Data collected through STAHR both locally and at CDC, are stored and accessed by a survey identification number. Other data collected through STAHR, while sensitive, are not personally identifying. This information includes drug use which is associated with HCV infection, medical conditions related to HIV, STD, and hepatitis diagnosis and testing, history of incarceration, alcohol use, residential zip codes, and income.

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

Information collection does not involve web-based data collection methods nor refers respondents to websites.

2. Purpose and Use of the Information Collection

The purpose of this pilot project is to improve the quality and completeness of national hepatitis C surveillance by including young IDUs that would not have been identified by the traditional surveillance system for acute HCV infection. Accordingly, the long-term intent of the STAHRS project is to provide a framework for active national surveillance for HCV in IDUs as part of an expanded national hepatitis surveillance system.

HCV is among the 60 national notifiable diseases that are reported through the National Notifiable Disease Surveillance System. Through this passive system less than a 1000 cases of acute hepatitis C virus (HCV) infection are reported each year. Since blood transfusion is no longer a risk, many of these are putatively injection drug users (IDUs); however, this information is usually not collected at the local level and even less frequently reported to CDC. In the absence of additional efforts to reach hard-to-reach at-risk population, passive surveillance for hepatitis C infection will never reach its full potential of representing all persons at risk for hepatitis C and will continue to under-represent the burden of hepatitis in young IDUs.

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Data from STAHR will be used to develop surveillance strategies that state and local health departments can implement without extraordinary effort. Using serial cross-sectional seroprevalence surveys, CDC and local health departments will be better able to estimate the magnitude and trends of acute HCV infection in this population. In turn, this project will increase access and understanding of this marginalized and hard-to-reach population and inform targeted vaccinations, prevention messages, and care.
We anticipate that one or more of the three recruitment methods used in STAHRS--street outreach method, respondent-driven sampling method, and venue based recruitment method--will be suitable for use in serial cross-sectional seroprevalence surveys among IDUs when serial surveillance becomes integrated into the local health departments' hepatitis surveillance. Findings from these focused, intensive investigations, in turn, will facilitate larger surveys that can be generalized to broader populations of young IDUs.

Further, we anticipate that the automated computer-assisted self interview ('ACASI') used in STAHR will become part of the health department survey tool. For national HCV surveillance, the ACASI survey will be shortened but still include questions about drug-use and sexual behaviors use of injection paraphernalia, etc. Many of the questions will focus on barriers to hepatitis care or to getting treatment for drug addiction. The choice of the questions ultimately used in each module might vary with the location, the venue where the young IDUs are reached and the comfort level of the IDUs with the health department survey staff charged with HCV surveillance.
Active serial surveillance for viral hepatitis in IDUs is a new strategy that will require trained staff with extra resources in order to be implemented in a routine fashion by the local health departments. Thus, the STAHRS project will also identify the personnel, training, and additional resources essential to integrate serial surveillance as a component of the notifiable disease surveillance at the state or local health departments. Eventually, serial surveillance may be extended by the local health departments to infections other than HCV.

CDC is most interested in finding ways of incorporating not only HCV and other infectious disease surveillance into its surveillance systems, but improving and expanding its behavioral surveillance projects. The detailed questionnaire used in STAHRS is expected to identify the questions that are relevant to effective behavioral surveillance among IDUs. In particular, STAHRS would identify the questions and information most likely to delineate drug use behavior, access to health care and drug treatment and other information that can then be targeted for intervention. Incentives are integral part of studies involving any hard-to-reach population. Projects that target IDUs have given incentives to increase participation. e anticipate that incentivizing participation for certain hard-to-reach groups such as the young IDUs will be explored when the national surveillance is implemented.

HCV testing will be the pillar of the long-term surveillance project for blood-borne infections. In this pilot we intend to test the ease or complexity of sample collection by different recruitment methods and to determine the prevalence of HCV by the different recruitment methods. This will be accomplished by merging this information to the survey data—i.e., determine the proportion of participants who learn their HCV status first time during this survey, and estimate the baseline seroprevalence for the serial cross-sectional seroprevalence survey.

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Both serological and molecular testing will be conducted on samples collected from consenting individuals in the STAHR project. The serological test results will be used to determine the prevalence of markers of HCV infection. The molecular testing (HCV RNA) that will be completed on HCV-seronegative samples will be used to determine possible early HCV infection (acute infection).

Finally, STAHR data may be used to assess progress in performance goals of CDC's National Center for HIV/AIDS, viral hepatitis, STD, and TB Prevention (NCHHSTP) to: 1) increase the proportion of people who consistently engage in behaviors that reduce risk of hepatitis transmission or acquisition; 2) track the prevalence of disease; 3) monitor behaviors that increase the risk of hepatitis C infection (among those who are not infected); and 4) provide locally relevant data for community planning.

After identifying a recruitment method that yields a large number of young IDUs, a seroprevalence survey will be conducted to determine the baseline prevalence of HCV infection, demographic characteristics of the participants and the baseline prevalence of risk factors for HCV infection. At a frequency to be determined on the basis of the analysis of information obtained from this pilot project, seroprevalence surveys will be completed in the same population and data collected will be compared with previous data. With repeated surveys in the same population trends in seroprevalence and risk factors will be determined. The difference in seroprevalence rate over time will indicate to the changes that occurred in incidence over time. This same approach will be applied by local and state health departments to estimate the overall prevalence of HCV infection and new infections in the United States.

Privacy Impact Assessment

During this pilot STAHR will collect the date of birth in order to determine eligibility to participate in this study and to identify participants who have completed the survey more than once. Records that have the exact same date of birth will be compared by date of survey and other demographic information such as race, education, and zip code; determinations of whether a record is a duplicate (i.e., a participant has previously taken the survey) will be made based on how closely this information matches. Data collected through STAHR, both locally and at CDC, 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.

Other than date of birth, no identifying information is collected. With the safe guards described above to protect the security and confidentiality of the data, the impact on privacy is expected to be minimal and limited. In addition, these safeguards are in place to prevent breaches of confidentiality. 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 contractor. This information will not be provided to CDC.

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3. Use of Improved Information Technology and Burden Reduction

STAHR will use a state-of-the-art computer-based audio, computer-assisted self-interview (ACASI) installed in secure laptop computers assigned to STAHR staff interviewers. Responses will be automatically recorded in the secured laptop computers minimizing the burden to respondents and interviewers. The interview instrument will be developed using Questionnaire Development System (QDS) software (NOVA Research Company, Bethesda, Maryland). The eligibility screener (Attachment 3) will be administered by trained STAHR staff. If eligible for the survey and the participant consents, the interviewer will instruct the participant on how to self-administer the remaining interview on the laptop computer. Previous studies have shown that respondents are more likely to reveal engaging in sensitive behaviors in a computer-assisted self interview without an interviewer than in a face-to-face format (Gribble, Miller, et al., 1999).

Data linking peer recruiters and recruits using RDS will be entered directly into a computer program, called "Coupon Manager." By entering data directly into the computer, the efficiency of data collection is improved as compared to using paper and then entering the data. The Coupon Manager program also reduces the time and effort to validate coupons and tracks payments of incentives. During a participant's visits to the field site, 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 Coupon Manager linking recruiters and recruits is also used in analysis and weighting to produce adjusted estimates.

Refusal to answer sensitive questions on research study questionnaires is an ongoing concern for substance abuse researchers. The use of consent forms that explain the purpose of the research study, how the data will be used, and the methods used to protect the confidentiality of the participant and their responses, have all served to improve responses to sensitive questions. In addition, questions are designed to be non-judgmental and are reviewed by members of the target population for accuracy, sensitivity and cultural appropriateness.

Over the past decade, a growing number of researchers have turned to computerized interviewing methods, such as Audio Computer Assisted Self Interviewing (ACASI), which has been shown in several studies to increase the frequency of response to sensitive question when compared to interviewer-administered questionnaires that asked the same questions. Using ACASI, study participants sit at a computer in a private location away from study personnel and other participants, and respond to questions that appear on the computer monitor and the participant listens to using headphones. This method eliminates the motivation for participants to provide socially desirable responses to sensitive or potentially stigmatizing questions. In our prior studies, including the CDC-funded CIDUS III/DUIT study, we have employed all of these techniques, through which we had very low rates of refusal to answer research questions. Among 3,285 IDUs age 15-30 years-old from five US cities, refusal rates ranged from <1% to <4% for the most sensitive questions on the hour-long baseline assessment. The table below shows the refusal to answer rate for specific questions in the CDC-funded CIDUS III/DUIT study among IDU respondents. Similar results have been obtained by other IDU researchers. Given that we will employ identical techniques in our proposed pilot study, we expect similarly low refusal rates.

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Response Refusal Rate to Selected Sexual and Injection Risk Variables, Among 15-30 Year-Old IDUs, CIDUS III/DUIT Study, 2002-2004 (n=3,285)

Variable	Total # Refusing to Answer	% Refusing to Answer
Age of first injection	16	0.49
During the past 3 months, what did you inject most often?	23	0.70
Did you inject at least once a week, every week, for the last 3 months?	16	0.49
Where were you most often when you injected?	42	1.28
In the past 3 months, how often did you inject with needles that had been used before you by somebody else, even if the needle was cleaned first?	51	1.55
Of the different people you injected with in the past 3 months, with how many different people did you share a cooker, cotton, or rinse water?	26	0.79
In the past 3 months, how many times did you have vaginal sex with female casual and/or sextrading partner(s)?	75	2.28
What is the HIV status of closest male steady partner?	87	2.65
What is the HIV status of closest female partner?	71	2.16
In the past 3 months, how many times did you have anal sex with all male casual and/or sex-trading partner(s)?	68	2.07
Have you ever exchanged sex for money or drugs?	47	1.43
In the past 3 months, how often have you asked a sex client/customer to use a condom?	63	1.92
What is your sexual orientation?	48	1.46
As a child, were you ever beaten, physically attacked, or physically abused?	52	1.58
As a child, were you ever sexually attacked, raped, or sexually abused?	57	1.74
In the past 3 months, how many steady female partners have you had vaginal, anal, or oral sex with?	86	2.62
In the past 3 months, how many casual female partners have you had vaginal, anal, or oral sex with - by that we mean "non-steady" or sex-trading partners?	104	3.17
(Males) In the past 3 months, how many steady male partners have you had anal or oral sex with?	115	3.50
(Females) In the past 3 months, how many casual male partners have you had vaginal, anal, or oral sex with – by that we mean "non-steady" or sex-trading partners?	37	1.13

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(Males) In the past 3 months, how many casual male partners have you had anal or oral sex with - by that we mean "non-steady" or sex-trading partners?	127	3.87

The incremental cost of each collected survey decreases with each subsequent interview conducted, so that when collecting more than 195 interviews, it is less expensive to use the handheld computer than paper. Although STAHR will use laptop computers and ACASI technology, the findings from this evaluation are expected to be true for STAHR because the overall cost of laptop computers used for STAHR is expected to be less than the overall cost of the handheld computers in the evaluation. Also, the difference in cost between the laptops and handheld computers is expected to be about the same that it would cost to add audio files to the computer program in the initial evaluation. Adding the audio component may add a marginal cost to the data collection, but the audio component is important because of the low literacy rate in these populations.

CDC will conduct training and site visits to provide instructions and technical assistance on how to use the interview software, conduct the interviews, archive the collected data, and transfer the data. CDC will also provide training, with detailed instructions on methods for conducting the interviews, to participating state and local health departments. CDC will require local STAHR staff providing supervision on the project to monitor interviewers regularly. CDC will convene lessons learned meetings to understand the problems that can occur with the software and hardware that are 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 grantees conducting STAHR.

The STAHR data files must be transferred, or uploaded, from the laptop computers to the project area's secure storage drive on a frequent basis. All STAHR data files must be transmitted to CDC using the Secure Data Network (SDN). CDC is investigating several software products which will enhance the security of data stored on the laptop computers. It is anticipated that this software will be installed on the laptop computers prior to the start of data collection in fall 2008.

4. Efforts to Identify Duplication and Use of Similar Information

A review of currently-funded programs did not identify potential areas of duplication. No known department or agency has carried out comparative studies of recruitment methods among young IDUs. Program reviews and national consultations were conducted to identify potential areas of duplication; however, none were found to exist.

CDC also performed an extensive literature search for similar methodological studies and found no similar studies.

Within 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:

- Supplement to HIV/AIDS Surveillance Project (SHAS) (OMB 0920-0262) exp. 06/30/2004

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- Medical Monitoring Project (MMP) (OMB-0920-0740) exp. 06/30/2010
- Never in Care (NIC) (OMB 0920-0748) exp. 08/31/2010
- National HIV Behavioral Surveillance (NHBS) (OMB 0920-XXXX, currently under OMB review)

None of these projects had information that could improve the recruitment of young IDUs for hepatitis incidence estimates.

5. Impact on Small Business or Other Small Entities

No small businesses will be involved in the proposed data collection.

6. Consequences of Collecting the Information Less Frequently

STAHR data collection activities will take place from 2008-2009. Data from this pilot survey will be used to create a revised protocol and questionnaire that can be implemented for ongoing, systematic data collection among young injection drug users in multiple cities in the United States.

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

The 60-day notice for this data collection was published with a different title, "*Pilot Project to Estimate the Incidence of Hepatitis C Virus Infection Among Young Injection Drug Users Using Serial Cross Sectional Seroprevalence Surveys"*. The public notice appeared in the *Federal Register Vol. 72. No. 148 Thursday, August 2, 2007 pages 42413-14.* A copy of this publication is attached (Attachment 2). We did not receive public comments.

The following persons participated in the design of this study.
Richard Garfein, PhD, Associate professor, UCSD
John Ward, MD, Director, Division of Viral Hepatitis, NCHHSTP, CDC.
Steven Wiersma, MD, MPH, Associate Director for Science, Division of Viral Hepatitis, NCHHSTP, CDC.
Deborah Holtzman, PhD, Senior Behavioral Scientist, Division of Viral Hepatitis, NCHHSTP, CDC.
Scott Holmberg, MD, Chief Epidemiology and Surveillance Branch, Division of Viral Hepatitis, NCHHSTP, CDC.
Ian Williams, PhD, MS, Team leader, Epidemiology team

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9. Explanation of Any Payment or Gift to Respondents

Incentives are integral part of studies involving any hard-to-reach population. and STAHR is no exception. Incentives will be used in STAHR as the project seeks to conduct surveys with hard-to-reach and highly selective populations and ask them highly sensitive questions about issues such as substance use and sexual behavior (Kulka, 1995).

Persons who are eligible to participate in this interview will be offered $25 in cash, gift certificates, cash cards, or bus or subway tokens, as an incentive to participate. 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 (Heckathorn, Semaan, et al., 2002; Ramirez-Valles, 2005; Wang, 2004). Use of incentives has been found to effectively improve participation of hard-to-reach and highly selective populations when posing highly sensitive questions about issues such as substance use and sexual behavior (Kulka, 1995). A dual-incentive system is a standard part of the RDS methodology in which participants receive an incentive for completing the survey and for recruiting their peers.

The need for and the amount of incentives proposed in this ICR is based, in part, on the fact that other, similar research projects that ask HIV risk behavior questions among populations at increased risk for HIV infection offer similar incentives. Thus, STAHR would be competing with local researchers who do offer incentives; without incentives, it is likely that participation would be low (McKnight, 2006; Stueve, 2001; Valleroy, 2000). 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); and NHBS (OMB 0920-0770, exp 03/31/2011). Each of these projects collects information for similar questions of populations other than IDUs and has a similar length of time for completing the survey.

In addition, all participants who return for their HCV test results will be offered $10.00 and participants who receive vaccination for hepatitis A and hepatitis B will be awarded $5.00. Provision of hepatitis A and B vaccinations at no cost is also considered an incentive to participate. On the basis of the findings from previous studies it is estimated that the prevalence of HCV infection among the participants in this project may be as high as 50% depending on the number of years they have been injecting drugs. Thus, this project creates the opportunity for health researchers to identify these cases and refer them to care. Participants should know their status in order to be referred to care and thus such incentives that increase the likelihood that a participant returns to collect the results of their tests increases the opportunity to offer the necessary information for prevention counseling and linkage to care.

10. Assurance of Confidentiality Provided to Respondents

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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 vaccination status of the participants. The link will be deleted prior to transmitting any data to CDC.

Documents containing personal identifying information including consent forms, laboratory, and vaccination tracking forms will be kept by the contractor, the University of California at San Diego (UCSD), in locked file cabinets and in password protected computers. Only UCSD project staff will have access to this information in order to identify participants for post-test counseling and referral for vaccination and hepatitis medical services as appropriate. UCSD will transmit data to CDC without identifying information and any reports that are prepared will present the data only in aggregate form.

All identifying information will be destroyed at UCSD, within 6 to 9 months of the completion of the project period; after the participant has submitted information regarding completion of the hepatitis A and B vaccination series and has received post-test counseling regarding his/her HCV test results.

The National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention has determined this project to be research however CDC is not engaged. CDC's role is to provide technical support and has no involvement or interaction with human research participants (Attachment 5). The contractor (UCSD) has submitted the protocol to the UCSD IRB for review and approval.

Audio tapes or other visual media will not be used in this study.

Privacy Impact Assessment

A. STAHR interviewers and data managers at UCSD will undergo security and confidentiality training as required for San Diego County health department staff. A number of required protections ensure the security of the data on laptop computers. The laptop computers are used solely for STAHR data collection activities. STAHR data are encrypted when stored on a laptop computer. Laptop computers are protected by using a coded password only known by authorized STAHR 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. UCSD will transmit STAHR data to CDC using the internet-based system that is 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 STAHR 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). No identifying information for any participant will be transmitted to CDC.

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B. The UCSD IRB has reviewed and approved the protocol and consent form for the STAHR project. This project will obtain consent from respondents prior to the administration of the interview instrument. 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 6. 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 section 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 interviewer-administered portion of the interview will be conducted by trained STAHR 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.

C. The consent form also informs the respondent that participation in the survey is voluntary. Almost all the questions in the eligibility screener and behavioral survey 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.

11. Justification for Sensitive Questions

Because, HCV is efficiently spread through sharing of equipment used to inject illegal drugs sensitive data regarding illegal drug use, type of drugs, duration of injection, sharing of needles, and sharing of injection paraphernalia must be collected in order to understand factors related to injection-associated HCV infection. Other risks for HCV infection such as, sexual exposure, sexual behaviors including exchange of sex for drugs will be collected because the specific behaviors, experiences or conditions have been shown to be associated with HCV infection. STAHR defines clinical status of the persons on the basis of the medical information related to HCV status, STD diagnosis and testing, hepatitis diagnosis and vaccinations, history of incarceration in the preceding 12 months, alcohol use, sexual history, and income. Spatial analyses enable investigations of hot spots for IDU-related hepatitis transmission and a better understanding of the geographic distribution of disease and risk. Spatial analyses will also be used to evaluate the randomness of the respondent driven sampling method of recruitment.

Respondents will be asked about their race/ethnicity to understand the potential relationship of race/ethnicity in RDS recruitment methods and eventually to be able to describe the at-risk population by race/ethnicity. Respondents will not be asked to provide their SSN. Collection of the sensitive data will be used to understand barriers to engaging in protective behaviors and to using HCV prevention services.

The demographic information is needed to describe the basic characteristics of young IDUs participating in STAHR. The demographic information will be used to describe information in

subsequent relevant modules by age category, gender, race, socioeconomic status and level of education. .

The injection network module describes the injection related relationships and networks. These data will also be used to determine the network size and the characteristics of the networks and help to interpret differences between samples obtained from the three different recruitment strategies. This is important for understanding injection networks and how transmission occurs.

The injection drug use module addresses the specifics of the injected agents, preparation of drugs, sharing of drugs and injection paraphernalia, frequency of injection and place of injection. The questions on place of injection and injection partners are important for understanding injection networks and to explain the geographic distribution of injected agents and other risk factors. The questions in this module will also be analyzed with laboratory findings in order to learn risk behaviors linked to transmission. The sharing works module is supplementary to the "injection drug use" module. This module describes prevalence of sharing related risk behavior for transmission of HCV. Data from this module will be used in analysis to identify characteristics of needle sharing. In addition to injecting drugs, information on use of alcohol and drugs through non-injected routes, which can impact their cognitive function, decision making, and personal risk profiles, will be collected. These factors have been found to be useful in understanding risk factors for HCV infection in other studies.

The module on syringe exchange programs addresses the use of the San Diego Syringe Exchange Program to exchange clean needles. We seek to learn more about participant's knowledge about the program as well as get detailed information of their use and barriers to practicing safe injecting behaviors. Data from this module will be used in the analysis of clean needle availability. Along with the results of serological testing this information will be used to determine and compare the prevalence of HCV infection among attendants of the syringe exchange program. The overdose module will be used to capture overdose trends of IDUs.

Law Enforcement Interactions: This module is designed to measure the effect law enforcement interactions has on participants risk behaviors. Previous studies have found a link between law enforcement interactions to high risk behaviors among IDUs.

Injection Correlates: This module of 3 questions is linked to the sharing works module and tries to quantify frequency of syringe sharing with main injecting partner. Data from this module will also be included in the analysis of sharing patterns.

HCV transmission beliefs and HCV testing: This module addresses participants' beliefs, medication and HCV testing history. We will use this data in the analysis portion of the study.

HIV transmission beliefs and HIV testing: This module is identical to the HCV transmission beliefs and testing with focus on HIV beliefs and medical history for HIV. This module will also be used in the analysis portion of the study.

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Drug treatment: This module is designed to address any history of current or past participation in drug treatment programs. The use of these questions will aid analysis by identifying potential barriers or cofounders in the results. San Diego is very distinct in it population characteristics mainly due to it's proximity to Tijuana, Mexico. Because this is a pilot study that will be used to inform the larger national surveillance study, we want to make sure we don't misinterpret the results. We decided to include a question that captures the use of drug treatment programs in the US or Mexico.

Sexual Behavior: This module was designed to assess HCV risk behaviors by differentiating steady vs. non-steady partners. Previous studies have found differences between risk behaviors people engage in with a steady vs. non -steady partner. Even though this module looks very lengthy, we have strategically ordered questions so that the main questions are asked first and if the questions don't apply to them (i.e. they did not have sex with a female) they will skip all the female sex questions.

Past Sexual History: This module asks participant for age of first sexual encounter as well as sex trading history. These factors have been found to be useful in understanding risk factors for HCV infection in other studies.

Sex Correlates and General Correlates: These two modules address condom use, child and adult sexual and physical abuse and HIV and HCV knowledge. These factors will be used in the analysis to identify and correlate to risk behaviors.

Vaccination History: As mentioned in our call, this is module is of interest to the CDC because we want to capture history of Hepatitis A and B vaccines in our population. Additionally, this will also be included in the analysis and will inform the larger national surveillance study if there is a greater need for Hepatitis A and B education.

Social Support: This module consists of 3 questions which tries to target the level of support the participants feel they have. These questions will also be included in the analysis.

Tuberculosis: This module assesses tuberculosis history. This data will be help to identify co-infections of HCV and HIV with TB. TB has been linked to these diseases by previous studies.

STI questions: These six questions will assess other potential sexually transmitted infections commonly linked to high risk behaviors. This data will also be included in the analysis of co-infections.

Hepatitis Questions: These questions try to assess actual history of Hepatitis infections diagnosed by a doctor. This will be correlated with other variables in the study.

RDS Questions: This module describes the recruiter (seed) who gave them a coupon. This section will be skipped if participant was not in the RDS phase of the study. These data will also help to interpret differences between samples obtained from the three different recruitment strategies as well as identifying characteristics of the seeds and recruiter.

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Cross border questions: Tijuana, Mexico and San Diego, California share the world's busiest land border crossing. Due to its proximity to the U.S. there is a unique comingling effect of drug use between people that go back and forth between borders. This is one of the reasons we would like to assess risk behaviors that occur in Tijuana and the US and provide appropriate data results for the larger national surveillance stud. This data will also be included in the analysis.

The context in which questions are asked also help to overcome their potential sensitivity. There are several steps taken in STAHR 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 UCSD 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 use of computers and headphones for data collection addresses concerns about privacy the respondent might have (that others can see their answers or hear the question read to them by the computer).
- The core questionnaire, which contains the most sensitive questions, is self-administered by the participant.
- The payment of an incentive indicates clearly to the respondent that the information is important to the survey sponsors.

12. Estimates of Annualized Burden Hours and Costs

Under the STAHR protocol, a total of 1000 persons will be interviewed during the 2 years of the project; 250 in each of RDS and street outreach recruitment methods and 500 using the venue-based recruitment methods. The total annualized public burden is estimated to be 816 hours; 83 hours for selecting participants for interview and 733 hours for the administration of the computer-based self interview instrument. During the first year, CDC plans to complete 800 interviews and estimates screening 1000 at-risk persons for eligibility to participate. The consent form (Attachment 6) and the eligibility screener (Attachment 3) together are estimated to require 5 minutes to complete. Thee consent form and the interview (Attachment 4) are estimated to take 55 minutes to complete. The consent form to be used for respondents participating in the survey and blood specimen collection is included (Attachment 6). The annualized burden estimates apply only to respondents who complete the interviews. Potential respondents who opt out of the survey are excluded from calculations of the burden to the public.

Table 12.A Estimated Annualized Burden Hours.

Respondents	Form	Number of	Number of	Average burden per	Total burden

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		Respondents	Responses per Respondent	Response (in hours)	(in hours)
Young IDUs	Screener	1000	1	5/60	83
Eligible young IDUs	Survey	800	1	55/60	733
TOTAL				1	816

Table 12.B.Estimated Annualized Costs

The estimates for the hourly wages were derived from Bureau of Labor Statistics Wage Data (http://www.bls.gov/bls/wages.htm)

Type of Respondent	Total Burden (in hours)	Average Hourly Wage Rate	Total Annual Respondent Cost
Young IDUs (screener)	83	$8.00	$664.00
Eligible young IDUs	736	$8.00	$5864.00
Total	816		$6528.00

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers
There are no costs to respondents other than their time.

14. Annualized Cost to the Federal Government
Table A. 14 provides information on estimates of annualized costs to the federal government. The personnel related to this data collection include a project officer at the GS-14 level and a GS- 9 level public health analyst/data manager. On average, about 20% of personnel time will be allocated to project activities. Travel is related to providing technical assistance and site visits as well as to attend interviewer training. STAHR is funded through a 2-year contract with University of California, San Diego in the amount of $624,608. This contract includes salaries, travel, equipment, and supplies and incentives. It also includes the data management, validation, and analysis needed to conduct the evaluation of the eligibility screener, questionnaire, and sampling method, which will be summarized in a final report of the pilot data. The government will also cover funds for development of the ACASI. The cost for the government during year 2 of the project will include only the annual salary and the travel costs.

Exhibit 14.1: Estimates of Annualized Costs to the Federal Government
The total annualized cost for this study is estimated to be $356,674. This includes the CDC FTEs and a contractual fee to UCSD. Details of the annualized costs are based on estimates provided by UCSD which will carry out the data collection activities. This contract includes salaries, travel, equipment, and supplies and incentives. It also includes the data management, validation, and analysis needed to conduct the evaluation of the eligibility screener, questionnaire, and sampling method, which will be summarized in a final report of the pilot data. Table A.14 includes the estimated cost of coordination with the CDC, data collection, analysis, and reporting.

Table A 14. Estimated Cost to the Government

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Expense Type	Expense Explanation	Annual Costs (dollars)
Direct Costs to the Federal Government	CDC Project Officer (GS-14, .25 FTE)	$35,228
	CDC Co-Principal Investigator (GS-12, .15 FTE)	$9,143
	Subtotal, Direct Costs to the Government	$44,371
Contractor and Other Expenses	UCSD Cost and Fees	$312,304
	Subtotal, Contracted Services	$312,304
	TOTAL COST TO THE GOVERNMENT	$356,675

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Table A.16: Project Time Schedule

Activity	Time Schedule
Begin field work	1 month after OMB approval
Complete field work	15 months after OMB approval
Initial Tabulation of Results	15-18 months after OMB approval
Data management and validation	15-16 months after OMB approval
Final data analysis	15-18 months after OMB approval
Dissemination of results	18-24 months after OMB approval

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

There is no request for an exemption from displaying the expiration date for OMB approval. The OMB expiration date will be displayed on the laptop computer in the questionnaire program.

18. Exceptions to Certification for Paperwork Reduction Act (PRA) Submissions

There are no exceptions to the Certification for Paperwork Reduction Act submissions.