REQUEST for Project Determination and Approval -- NCHHSTP ADS OFFICE

This form should be used to submit to NCHHSTP ADS proposals for projects and activities involving CDC investigations prior to initiation that do not require routing to the CDC Human Research Protection Office. Projects are eligible for this classification are (1) research that do not involve "human subjects" where the primary intent is not to generate generalizable knowledge, (2) research projects that do not involve identifiable human subjects, or (3) research projects in which CDC is not "engaged". (See page 3 of this form for helpful definitions and weblinks.) These projects do not require submission to the CDC Human Research Protection Office (HRPO) for human subjects research review. Do **NOT** use this form for "exempt" research that must be routed to HRPO.

Project Title_Pilot project to estimate the incidence of Hepatitis C virus infection among young injection drug users using serial cross sectional seroprevalence surveys _____

Project Locations/Sites: _San Diego_____

Project Officer(s)_Eyasu Teshale, MD_____ Division:____DVH_____ Telephone: __404-718-8553_____

Proposed Project Dates: Start: 09/24/2007 End: 09/23/2009

Please check appropriate category and subcategory:

___I. **Activity is not human subjects research.** Primary intent is public health practice or a disease control activity.
- ___A. Epidemic or endemic disease control activity; collected data directly relate to disease control needs.
- ___B. Routine disease surveillance activity; data used for disease control program or policy purposes.
- ___C. Program evaluation activity; data are used primarily for that purpose.
- ___D. Post-marketing surveillance of efficacy or adverse effects of a new regimen, drug, vaccine, or device.
- ___E. Laboratory proficiency testing.

___II. **Activity is not human subjects research.** Primary intent is public health program activities
- ___A. Public health program activity (including service delivery, health education, social marketing campaigns, program monitoring and process measures, and risk reduction interventions).
- ___B. Activity is purely administrative (e.g., purchase orders or contracts for services or equipment) and not related to research

___ III. **Activity is research but does NOT involve identifiable human subjects.**
- ___A. Activity is research involving collection or analysis of data about health facilities or other organizations or units which are not individual persons.
- ___B. Activity is research involving data or specimens from deceased persons.
- ___C. Activity is research using unlinked or anonymous data or specimens: **ALL** (1-4) of the following are required:
  - ___ 1. No contact with human subjects is involved for the proposed activity...**and**...
  - ___ 2. Data or specimens are/were collected for another purpose...**and**...
  - ___ 3. No extra data/specimens are/were collected for this purpose...**and**...
  - ___ 4. Identifying information was either: (one of these must be checked)
    - __a. not obtained
    - __b. removed prior to this submission so that data cannot be linked or re-linked with identifiable human subjects.
    - __c. protected through an agreement. The investigators and the holder of the key (code linking the data to identifiable human subjects) enter into an agreement prohibiting the release of the key to the investigators under any circumstances, until the individuals are deceased. Please attach a copy of the agreement.

_X__ IV. **Activity is research involving identifiable human subjects but CDC involvement does not constitute "engagement in the research".** :
- __A. This project is conducted under a grant or cooperative agreement award mechanism. **ALL** of the following 3 elements are required:
  - ___1. CDC employees or agents do not intervene or interact with living individuals for research purposes.
  - ___2. CDC employees or agents do not obtain individually identifiable private information.
  - ___3. Project must be reviewed by an IRB with an FWA. (Attach a copy of the IRB approval letter from the engaged institution(s).
    Supported Institution/Entity Name ___University of California, San Diego _____
    Supported Institution/Entity FWA #_ FWA00004495___ Expiration Date___04/13/2010_____
    Local IRB # _Pending_____ IRB Approval Expiration Date_____
- _X__B. CDC staff provide technical support only that does not involve interaction with human subjects or with data collection.
- ___C. CDC staff are involved only in manuscript writing for a project that has closed. For this project, CDC staff were not

involved with human subjects or with data collection.

Attach project description (standard format at end of this form) in enough detail to justify the proposed category. Submit through division ADS/Director to: nchstphs@cdc.gov

☐ ___ Check here if this request is an **amendment** of an existing determination of human subjects research review routing.

Approval initials & Name: _____ 01/22/2008 _____ 1/24/08
Branch or Section Chief Date **ADS or Div. Director** Date

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Project Title_ Pilot project to estimate the incidence of Hepatitis C virus infection among young injection drug usersusing serial cross-sectional seroprevalence surveys _____

NCHSTP ADS Review **Date received in NCHSTP ADS Office:** Feb 4. 08

✓ **___Concur, project does not require human research review beyond NCHHSTP**

or

___Project constitutes human subjects research that must be routed to CDC HRPO

Comments/Rationale: - Should the role of CDC project officer change [redacted] in scope to require a different determination or review process, please advise the ADS office of NCHHSTP.
- Please provide the ADS Office of NCHHSTP with a copy of local IRB approval

Additional Comments:

1. This form cannot be used to document human subjects research that is exempt from human subjects regulations; such researchmust instead be submitted to the CDC HRPO.
2. Although CDC HRPO review is not required in this instance, investigators/project officers are expected to adhere to ethical principles and standards by respecting and protecting to the maximum extent possible the privacy, confidentiality and autonomy of participants. All applicable State and Federal privacy laws must be followed.
3. Although this project does not require routing to CDC HRPO, informed consent may be appropriate. Information disclosed in the consent process should address the eight standard consent elements as adapted to the project.
4. Other: and the Best. SS

Signed: _____ Feb 12. 08
Name: Salaam Semaan
Date
Associate (or Acting ~~or Deputy Associate~~) Director for Science, NCHHSTP
National Center for HIV, Viral Hepatitis, STD, and TB Prevention

Pilot Project to Estimate the Incidence of Hepatitis C Virus (HCV) Infection among young Injection Drug Users (IDUs) Using Serial Cross-Sectional Seroprevalence Surveys

Project Title: Pilot Project to Estimate the Incidence of Hepatitis C Virus (HCV) Infection among young Injection Drug Users (IDUs) Using Serial Cross-Sectional Seroprevalence Surveys. The project acronym "PIHCS" is for Pilot IDU Hepatitis C Study.

Principal Investigator:

Richard S. Garfein, PhD, MPH
Associate Professor
Division of International Health & Cross Cultural Medicine,
Department of Family and Preventive Medicine,
University of California San Diego School of Medicine,
9500 Gilman Drive, mailstop 0622
San Diego, CA 92093

CDC Project Officer including roles and responsibilities:

Eyasu Habtu Teshale, MD
Epidemiology Research Team
Epidemiology and Surveillance Branch
Division of Viral Hepatitis
National Center for HIV, Hepatitis, STD, TB Prevention
Centers for Disease Control and Prevention
1600 Clifton Road, NE
Mailstop G-37
Atlanta, GA 30333

The Project Officer is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the contracting Officer changes in requirements; (2) interpreting the statement of work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

Other participants in research:

Division of Viral Hepatitis
Laboratory Branch

Sponsoring Institution:

This project is sponsored by Department of Health and Human Services, Centers for Disease Control and Prevention, Division of Viral Hepatitis.

Project Goal:

The goal of this project is to identify best method and venue for serial cross-sectional seroprevalence surveys to monitor incidence of HCV infection among young injection drug users.

Project objectives:

The objectives of this project are to (1) develop and pilot test different methods/venues for recruiting a sample of young IDUs that is representative of the population of young IDUs at risk for HCV infection in a defined geographic area, (2) develop and pilot test instruments for collecting data from young IDUs regarding demographics, risk factor for HCV infection, missed opportunities for hepatitis prevention, access to medical care, and knowledge, attitudes, and beliefs about HCV infection, and (3) determine the utility of HCV nucleic acid testing (NAT) and HCV antigen-antibody testing to identify sero-incident infections among young IDUs.

Program needs to be addressed:

Currently the Centers for Disease Control and Prevention (CDC) monitor the national incidence of acute hepatitis C through passive surveillance of acute, symptomatic cases of laboratory confirmed hepatitis C. Identifying and reaching persons at risk for HCV infection to provide risk-reduction counseling is critical to prevent infection. However, only a minority of people with acute infection have symptoms (<25%) and passive surveillance only 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. Injection drug users (IDUs), who are the primary risk group for acute hepatitis C (70% of identified acute cases), have additional barriers to health care access and/or utilization resulting in the potential for a further underestimation of overall incidence. Thus, it is necessary to consider strategies other than passive surveillance for incidence monitoring. Better methods of identification of persons at risk will enhance current surveillance efforts to monitor the incidence of HCV infection. Methods developed in this study can be used in other areas to gather representative data on incidence of acute disease and the burden of disease caused by HCV infection.

In this project, instruments for collecting behavioral/risk factor data from IDUs will be developed and pilot tested. The utility of using HCV NAT, HCV antigen-antibody testing and other testing modalities to identify sero-incident (window period) infections will also be assessed. It is estimated that data will be collected over 15 month period from a total of 1000 respondents.

The information collection will be used to address gaps in knowledge about how to conduct surveillance for acute HCV infection among young injection drug users (IDUs). CDC in collaboration with the University of California, San Diego (UCSD) has developed a recruitment strategy and is developing a behavioral questionnaire specifically targeting young IDUs. The PIHCS is a pilot to develop and test different methods to recruit a sample of young IDUs that is most representative of the population of young IDUs at risk for HCV infection in a defined geographic area. This pilot study will determine the feasibility of using the different recruitment venues/methods for an ongoing surveillance system.

Population to be studied:

The population to be studied in this project includes young injection drug users (age 18-30 year) who self-report drug use during the past six months and are residents of the city of San Diego, CA that are recruited either through the venue based, street outreach, or respondent driven sampling methods.

Methods:

The selection of appropriate methods to recruit injection drug users is complicated by the fact that population-based samples of these groups are not feasible as they cannot be easily identified as drug users or enumerated for sampling purposes. Several guiding principles determined the selection of methods to conduct this survey. These principles included the selection of methods that would 1) result in the most representative sample possible, 2) be feasible for implementation in the heterogeneous venues/methods eligible for conducting the recruitment, and 3) allow for standardized recruitment of at least 250 young injection drug users. Persons between 18-30 years of age who self-identify as having injected drugs in the past six months will be identified from three venue/methods at the locations identified as part of project activities. The following three venut/methods are employed to identify a total of 1000 eligible respondents for this study.

Respondent driven sampling (RDS) will be used to recruit at least 250 young injection drug users. RDS is a chain-referral sampling strategy similar to snowball sampling. It starts with a limited number of "seeds" who are chosen by referrals from people who know the local young injection drug user population well, or through outreach to areas where young injection drug users can be found. Seeds complete the survey (eligibility screener and survey) and then are asked to recruit a specified number (usually between 3 and 5) of young injection drug users they know who meet the eligibility criteria for the study. These persons, in turn, complete the survey and are asked to recruit others. This recruitment process continues until the sample size has been reached.

Passive Street outreach recruitment: At least 250 eligible participants will be recruited by passive methods such as leaving posters and leaflets at recruitment locations, posting messages on e-mail list serves utilized by young IDUs, and encouraging participants to tell their friends or people they know about the study. Locations identified as part of preliminary activities shall be used for recruitment. The method of sampling at passive

street outreach yields a convenience sample of young IDUs. Recruitment will stop when the desired number of participants is recruited or when the study period is over.

Venue based recruiting: At least 500 participants will be recruited from two different venues (250 from each) that are known to provide services/have access to populations that include a substantial proportion of young IDUs. Based on the estimated number of young IDUs that receive services at these venues the recruitment will include every consecutive eligible person until the sample size is satisfied. The two venues will include 1) a syringe exchange program, and 2) a sexually transmitted disease (STD) clinic.

Sampling Methodology:

Respondent driven sampling (RDS) will be used to recruit at least 250 young injection drug users. RDS is a chain-referral sampling strategy similar to snowball sampling. It starts with a limited number of "seeds" who are chosen by referrals from people who know the local Young injection drug user population well, or through outreach to areas where young injection drug users can be found. By starting with a small number of seeds (between 3 and 5), limiting the number of individuals each participant can recruit, and allowing a significant number of recruitment waves to occur, the distribution of the final sample begins to resemble the underlying eligible population living in the project area and is unbiased by the characteristics of the seeds (Heckathorn, 1997; Heckathorn, 2002).

The statistical theory upon which RDS is based suggests that if peer recruitment proceeds through a sufficiently large number of waves, the composition of the sample will stabilize, becoming independent of the seeds from which recruitment began, and thereby overcoming any bias the nonrandom choice of seeds may have introduced (Heckathorn, 1997; Heckathorn, 2002). This stable sample composition is termed the "equilibrium." Experience with RDS indicates that equilibrium can be achieved in approximately 6 waves. Another factor that has an impact on how quickly equilibrium can be reached is called "homophily." This refers to the degree of insularity, or in-group preference for recruitment. The more insular a group, the more likely they are to recruit others like themselves and it would take more waves to reach equilibrium. Having a diverse set of seeds will help ensure diversity of networks with regards to their degree of insularity included in the initial waves.

The sampling frame for RDS is created during the sampling process. The frame is based on specific information collected from participants regarding who recruited them and their network size. Recruitment is tracked; recruiters can be linked to those they have successfully recruited using the Coupon Manager software. Information on who recruited whom is used to calculate cross-group recruitment proportions. The participant's personal network size is based on how many people they know who fit the eligibility criteria for the project.

To calculate the population estimates and variances derived from RDS, several sources of bias are taken into account: 1) the differences in effective recruitment across groups (those more effective at recruitment would be overrepresented in the sample); 2)

homophily (groups that are more insular would be overrepresented because it is more difficult to "break out" of those groups; and 3) the network size (groups with larger networks would be overrepresented because more recruitment paths lead to their members). The population estimates derived from RDS are applicable to the underlying eligible transgender population.

Passive Street outreach recruitment: At least 250 eligible participants will be recruited by passive methods such as leaving posters and leaflets at recruitment locations, posting messages on e-mail list serves utilized by young IDUs, and encouraging participants to tell their friends or people they know about the study. This method yields a convenience sample of young IDUs. Recruitment will stop when the desired number of participants is recruited or when the study period is over.

Venue based recruiting: At least 500 plus participants will also be recruited from two different venues (250 from each) that provide services/have access to populations that include a substantial proportion of young IDUs. Based on the estimated number of young IDUs that receive services at these venues the recruitment will include every consecutive eligible person until the sample size is satisfied. Recruitment will stop when the desired number of participants is recruited or when the study period is over.

Incentives to be provided:

Incentives will be used in PIHCS 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). Because the interview, the pretest counseling for HCV testing, and the blood draw will take approximately 1 hour to complete, to increase response rates eligible persons will be offered an incentive to participate. With increased response rates, the reliability of the data will be improved as the samples will be more representative of the underlying populations of interest. Participants will be given approximately $25 in cash for participation in the interview. If local regulations prohibit cash incentives, equivalent incentives may be offered in the form of gift certificates, cash cards, or bus or subway tokens.

To increase peer recruitment in RDS, additional incentives will be provided to those who recruit an eligible participant who completes the survey (the "recruiter reward"). Recruiter rewards will be approximately $10 for up to three peer referrals, which is standard for RDS studies (Heckathorn, Semaan, et al., 2002; Ramirez-Valles, 2005; Wang, 2004). 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. As with the survey incentives, if local regulations prohibit cash incentives, equivalent incentives may be offered in the form of gift certificates or cash cards.

The need for and amount of incentives is based, in part, on the fact that other similar research projects that ask HCV risk behavior questions among populations at increased risk for HCV infection offer similar incentives. Thus, PIHCS 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 including CIDUS I and DUIT. Each asks questions similar to those in PIHCS and has a similar length of time for completing the survey. These incentives were used to help increase participation rates; participants were offered approximately $25 as an incentive.

In addition, all participants who complete HAV and HBV vaccination series will be awarded $5.00 and this will motivate participants to complete the recommended dose of vaccination according to schedule.

Plans for data collection and analysis:

All interview data will be collected electronically to minimize burden to respondents and interviewers. The final standardized interview instrument will be provided by CDC in an electronic format for use on a laptop computer. The interview instrument will be developed using Questionnaire Development System (QDS) software (NOVA Research Company, Bethesda, Maryland). The eligibility screener will be conducted by trained PIHCS staff. If the person is eligible and consents to completing the survey, the interviewer will instruct the participant on how to self-administer the remaining interview on the laptop computer. The core questionnaire will be conducted in a audio computer-assisted self-interview (ACASI).

Computer-assisted self interviewing reduces burden for the respondent. The computer customizes the question wording for each respondent. In addition, previous studies have shown that respondents are more likely to reveal engaging in sensitive behaviors in a computer-assisted self interview than in a face-to-face format.

Following pretest counseling, consenting participants will have two tubes (1 EDTA and 1 SST) of blood drawn via venipuncture by a trained phlebotomist. The EDTA tube will be spun and plasma aliquot into 2 cryovials (1.0 mL each) before freezing at -70 C for HCV nucleic acid testing at CDC. After centrifugation, serum from the SST will be used for anti-HCV testing at the San Diego County Department of Health Services Lab. The remaining sera will be placed into 2 cryovials (1.0 mL each) and frozen in a manner suitable for routine serologic testing. Cryovials will be labeled with the participant's unique ID number and date of blood draw.

The purpose of this pilot project is to develop and test different methods to recruit a sample of young IDUs that is representative of the population of young IDUs at risk for HCV infection in a defined geographic area and specific venue. These recruitment methods will be compared and contrasted to identify a methodology to be used in the future in an ongoing serial cross-sectional seroprevalence surveys among young IDUs. Data from the pilot survey will be used to develop surveillance strategies directed to young injection drug users using the venue and method of recruitment that yields the largest number of new infections among young IDUs that would not have been identified by the traditional surveillance system for acute HCV infection.

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. Furthermore, identification of persons with acute HCV infection allows public health practitioners to understand factors associated with new HCV infections in this era of decreasing incidence of HCV, to evaluate existing services to decrease HCV transmission, and to develop novel strategies to reduce new infections.

Being a pilot, PIHCS will not yield data that can be generalized to broader populations. The pilot data will be used to evaluate the extent to which prevalence/incidence data could be generalized if it were collected through a surveillance system using the best of the piloted methods. Thus, at best, data from the PIHCS pilot may be used to describe characteristics of young IDU by venue/methods of recruitment, behaviors related to HCV infection, and current usage of prevention efforts, including hepatitis testing.

Two primary papers are anticipated from this study; 1) Prevalence and Correlates of HCV Infection among 18-30 Year-Old IDUs in San Diego, CA; and 2) Similarities and Differences among 18-30 Year Old IDUs Recruited Using Different Recruitment Methods. These papers will be drafted by the PI and PO and may include additional co-authors from UCSD and CDC as deemed appropriate by the investigators. Abstracts may be submitted to scientific conferences by the PI and PO prior to the end of the study and the papers will be written within 1 year of completing data collection. In addition, the study data may be used by UCSD and CDC for secondary analyses leading to presentations and publications.

Confidentiality protections:

Information collected for this project will include name, date of birth, gender, race/ethnicity and area of residence. This information is collected by a contractor. None of the identifying information is transmitted to CDC. The main reason for collecting personal identifying information is to be able to identify each participant uniquely and to assign a unique ID for each participant. The only link between participants' names and IDs will be an electronic and paper file containing only these identifiers. The information obtained from the surveys and in the laboratory and vaccination database will be identified only by unique IDs.

Personal identifying information will be kept in a locked file cabinet and in a password protected computer file. Only local project staff will have access to identifying information and only for the purpose of identifying participants for posttest counseling and referral to vaccination and hepatitis medical services when needed. All other data collected for this project including consent forms, laboratory, and vaccination tracking forms will also be kept in locked file cabinet at project sites. These documents will be accessed only by the local project manager. CDC will receive a copy of these documents which will have no identifying information.

The identifying information will be destroyed after the participant had submitted information regarding completion of the hepatitis A and B vaccination series and had

received posttest counseling regarding his/her HCV test results. This means the all identifying information will be destroyed within 6 months of the completion of the project period.

The informed consent process for respondents may be fulfilled by obtaining a consent document signed by the respondent, or by having the interviewer sign a consent document attesting to the respondents' verbal consent. The study site will obtain consent from respondents and store the forms in a secure location, separately from other information collected from participants. Potential respondents who opt out of the survey will not be considered eligible to participate in the collection of blood specimens. Interviewers receive extensive instruction about the importance of safeguarding respondents' identity, and procedures to avoid breaching of confidentiality.

Audio tapes or other visual media will not be used in this study. Interview data will be collected using A-CASI and the generated data files will be de-identified after notes have been verified and no links will be maintained to any data collected.

Other ethical concerns/issues:

The necessary paperwork and protocol to seek IRB approval will be submitted to the UCSD IRB by 1/31/08.

Hepatitis A/B vaccination is available to high-risk adults through clinics and agencies throughout San Diego with eligibility linked to patient risk factors. Study participants will be referred to these venues to receive the vaccine.

Following pretest counseling, participants will have two tubes of blood drawn via venipuncture by a trained phlebotomist. Consent forms will include detailed information on the risks and benefits for respondents by participating in this project. After testing of blood samples by the San Diego County Department of Health Services Lab results will be communicated to respondents following the appropriate posttest counseling. The respondents will be referred for appropriate hepatitis C related medical care.

Projected time frame for the project:

Data from PIHCS are expected to inform future surveillance methods for acute HCV infection and data collection from young IDUs. The evaluation of the recruitment method will begin with data collection. CDC will monitor recruitment in each of the four project areas to evaluate the general efficiency and feasibility of RDS at recruiting 250 eligible persons; as well as the other methods general efficiency and feasibility in recruiting young injection drug users. After recruitment with the RDS method ends, data will be analyzed to examine whether the sample composition stabilized on key socially salient characteristics (e.g., race/ethnicity, age, or HIV status). For each socially salient characteristic, sources of sampling bias will be examined including: 1) the differences in

effective recruitment across groups; 2) insularity of the groups; and 3) differences in network size across groups. The following table shows the PIHCS Timeline.

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

Plans for publication and dissemination of the project findings:

Abstracts may be submitted to scientific conferences by the PI and PO prior to the end of the study and the papers will be written within 1 year of completing data collection. In addition, the study data may be used by UCSD and CDC for secondary analyses leading to presentations and publications.

Appendices, including informed consent forms:

Project PI will submit informed consent forms to the local IRB. CDC will receive a copy of the cleared protocol and consent forms.

References:

Heckathorn D. Respondent-driven sampling: a new approach to the study of hidden populations. Social Problems 1997; 44(2):174-199.

Heckathorn D. Respondent-driven sampling II: Deriving valid population estimates from chain-referral samples of hidden populations. Social Problems 2002; 49(1):11-34.

Heckathorn D, Semaan S, Broadhead R, Hughes, J. Extensions of respondent-driven sampling: a new approach to the study of injeciton drug users aged 18-25. AIDS and Behavior 2002; 6(1):55-67.

Kulka R. The use of incentives to survey "hard to reach" respondents:a brief review of empirical research and current research practice. Seminar on New Directions in Statistical Methodology, 1995 #23, 256-289. 1995. FCSM Statistical Policy Working Papers.

McKnight C, Des Jarlais D, Bramson H et al. Respondent-driven sampling in a study of drug users in New York City: Notes from the field. Journal of Urban Health 2006; 83(7):i54-i59.

Ramirez-Valles J, Heckathorn D, Vazquez R, Diaz RM, Carlson R. From networks to populations: The development and application of respondent-driven sampling among IDUs and Latino gay men. AIDS and Behavior 2005; 9(4):387-402.

Stueve A, O'Donnell L, Duran R, San Doval A, Blome J. Time-space sampling in minority communities: Results with young Latino men who have sex with men. American Journal of Public Health 2001; 91(6):922-926.

Valleroy L, Mackellar D, Karon J et al. HIV prevalence and associated risks in young men who have sex with men. JAMA 2000; 284(2):198-204.

Wang J, Carlson R, Falck R, Siegal H, Rahman A, Li L. Respondent-driven sampling to recruit MDMA users: a methodological assessment. Drug and Alcohol Dependence 2005; 78(5):147-157.

PILOT PROJECT TO ESTIMATE THE INCIDENCE OF HEPATITIS C VIRUS INFECTION AMONG YOUNHG INJECTION DRUG USERS USING SERIAL CROSS-SECTIONAL SEROPREVALENCE SURVEYS
INFORMED CONSENT

University of California, San Diego
Centers for Disease Control and Prevention

Flesch-Kincaid Grade Level = 7.8

A. Purpose of the Study

You are being asked to take part in a research study of a program to help stop the spread of HIV (the virus that causes AIDS) and hepatitis C virus (HCV, a virus that can harm the liver) among people 18 to 30 years old. The University of California, San Diego (UCSD) along with the Centers for Disease Control and Prevention (CDC) in Atlanta are doing this research. We hope to learn how young people who inject drugs get infected with HIV and HCV and create programs to help them avoid it. You are being asked to take part in this study because you are between 18 and 30 years old and have injected drugs.

Taking part in this research study is voluntary. The information that follows is given to help you make an informed decision whether or not to take part. We want to make sure no one, including the person who may have given you a coupon, has pressured you to join this study. If you have been pressured to join the study, please tell us. Please do not join the study only because someone wants you to join.

B. Procedures

If you choose to take part, the following things will happen:

1. You will be seen 2 times by the project staff, once today and once in about 2-3 weeks.

2. At today's visit you will fill out a survey with personal questions. The survey asks questions about your health, sex life, and drug use. You will fill out the survey on a computer so that no one will see your answers. A staff member will show you how to fill out the survey and will be nearby to help if you have problems. The survey takes about 30 minutes to finish. You may skip any question you don't want to answer and can stop answering questions at any time. You will also be asked to give us information about how to find you so that we can remind you of your next appointment. You can decide what information you feel is okay to give to us and how you want that information used.

3. After the survey, you will get pre-test counseling and have your blood drawn for HIV and HCV testing. The counseling will take about 15-20 minutes. A trained counselor will explain the purpose and possible results of the tests to you. He or she will also talk to you about the effect that getting the results could have on you. You will be told how to avoid getting or spreading HIV or HCV. The counselor can give you information about drug treatment and advice about drug use practices and safer sex. You can ask questions about your health. The counselor will offer you free condoms and bleach. The pre-test

counseling session may be observed so that project supervisors can see how the counselors are doing.

4. Two tubes, about 1.5 tablespoons, of blood will be drawn from one of your veins. It will be tested to see if you are infected with HIV and HCV.

5. If you agree, the research team would like to freeze and store some of your blood. The samples will be stored at a UCSD Lab and the CDC in Atlanta. Your samples might be used for studies done in the future and they would be linked to the other data about you collected in this study. Future tests will be limited to standard tests for HIV, HCV or other infections that may be spread through sex or injecting illegal drugs. For example, there might be a new test that will tell us more about the type of HIV or HCV you have or how long HIV or HCV has been in your body if you are found to be infected. Your sample will not be used for any genetic testing. Your blood will not be used for cloning or commercial purposes. Your samples will be stored with some data about you such as your study ID number, age, and sex. Your blood sample will be linked to the other data about you collected in this study. We will not have your name on the blood sample and will not share any results with another party, such as an insurance company. Six months after the study is over, there will be no way to know it is yours. Thus, we will not report back any results from this testing to you. Your blood will be stored indefinitely. That is, we do not know how long we will store your blood, but it may be for many years. You can still be in this study even if you do not want your blood to be stored for future studies.

I agree to storage of my blood at the UCSD Lab and the CDC in Atlanta and to be used for possible future testing.

Yes_____ No_____ _____

Signature

If you agree to storage of your blood now, but change your mind within six months after the end of the study, you may withdraw your consent. To withdraw your consent for testing of stored blood, contact Jazmine Cuevas, Project Coordinator at (619) 543-5010.

6. After your blood is drawn, you will get an appointment to come back within 2-3 weeks for your HIV and HCV test results. At that time, you will have a 20 minute counseling session on what your results mean. The counselor will talk to you about how to keep from getting or spreading HIV or HCV. He or she can give you information about drug treatment and advice about drug use practices and safer sex. You can ask questions about your health. The counselor will offer you free condoms and bleach. These sessions may be observed to allow project supervisors to observe how the counselors are doing. The counselor will also tell you about a vaccine (shots) that can protect you against other viruses (HAV and HBV) that can harm your liver. The vaccine is given in 3 shots over a six-month period. We are interested in how willing young people who inject drugs are to get these shots. If you choose to get these shots, we will ask you to tell us each time you receive a shot.

7. We may give you up to three coupons to give to other people you think might qualify for this study. The coupons tell people where they can get more information about this research. The coupons also have a number on them that will be linked to your study identification number so you can be compensated for referring people to the study.

8. Your part in the study will end after the second visit. However, you might be asked to take part in other studies. You may choose not to be in other studies if you wish.

C. Risks/Discomforts

Possible risks and discomforts you could have during this study include:

1. There may be questions on the survey that you find unpleasant or hard to answer. If there are questions that you do not want to answer, you do not have to answer them. Also, you can stop taking the survey at any time and withdraw from the study.

2. The study may involve sharing personal stories with the counselor. Some of these issues could make you feel uneasy or embarrassed. If there are questions you do not want to answer, you do not have to do so. Also, you can stop taking part in either session or the study as a whole at any time.

3. You may feel a small sting from the needle when your blood is drawn. There is a slight risk of bruising from the blood draw. The person who draws your blood is specially trained to make this risk small. Bruising of this type does not cause long-term problems. No drugs, blood, or other material will be put into your vein when blood is being drawn.

4. If you chose to get your test results for HIV and HCV, the results may upset you and cause you to feel afraid and depressed.

5. Even though we will do our best to keep your test results and everything you tell us private, it is possible that someone who should not have this information may see it.

D. Benefits

The potential benefits of your taking part in this study include:

1. You will be counseled about risk and how to prevent HIV and HCV infection, sexually transmitted diseases, and other health problems that can come from using drugs. We can also refer you for social services and health services. The referrals you get will depend on what you need and what services there are in your area.

2. You will get free HIV and HCV tests.

3. You will get help to find a drug treatment program if you ask for it.

4. You will be referred to a local hospital and other local groups for health services and support if you have HIV or HCV.

5. You will be told where you can get free vaccine (shots) that protect you against hepatitis A and B.

6. You will get education on safer injection drug use and preventing HIV, HCV and sexually transmitted diseases.

7. You will get bleach and condoms.

E. Confidentiality Statement

Information that you give us in this study will be kept private to the extent allowed by law. By law, we must report to the state suspected cases of child abuse (or if you tell us you are planning to cause serious harm to yourself or others). Also, if your test results show that you have HIV infection, the lab is required by California law to report these test results to the local health department by unique identifiers, which means your name will not be disclosed. In order to protect your privacy, we will give you a study ID number so your name will not be on the survey forms or test results. We will ask you for your name and address so we can remind you about your second visit or give you information that is important to your health. Your name and address will be kept separate from the survey forms and test results. A single sheet will be used to link your name with your study number. This sheet will be kept in a locked file drawer at the study office with access only to the principal investigator or senior project staff. This link will be destroyed 6 months after the end of the study. The information from this study may be published in scientific journals or presented at scientific meetings but your identity will be kept strictly confidential.

You will not be allowed to be in this study more than once. To prevent that, we will keep your name and other contact information in a computer file and in a locked file drawer at the study office, with access only to the principal investigator or senior project staff, until it is destroyed 6 months after the end of the study. Only study staff with a need for this information will have access to it.

F. Costs

There will be no costs to you as a result of taking part in this research study except transportation costs to and from the assessment site and your time.

G. Compensation

You will receive $25 for your time, travel and other expenses from taking part in this study. You will get $10 when you come back for the HIV and HCV test results visit. You will also get $5 each time (up to 3) you bring us a record showing that you received a dose of hepatitis A/B vaccine.

If you have been given coupons, you will receive compensation for telling people about the study who are qualified to join the study. To do this, you have to give the person a coupon and the person must give this coupon back to us. The person must be 18-30 years old and a current drug injector. You can do this for up to three people and you will receive $10 for each person who is screened by our study staff for the first time only.

H. Alternatives to Participation
An alternative would be not to take part in the study.

I. Offer to Answer Questions
Richard Garfein, Ph.D. will be in charge of this research study. You may contact him at (858) 822-3018 with any questions or concerns about taking part in the study. If you feel you have been injured as a result of taking part you may contact Jazmine Cuevas, Project Coordinator at (858)543-5010. If you have any questions regarding your rights as a research study subject, you may contact the Office of Human Subjects at (858) 455-5050. You will be given a copy of this form to keep.

J. Voluntary Participation and Withdrawal Statement
Your taking part in this research study is voluntary. Your choice of whether or not to take part will not interfere with your right to health care or other services to which you are otherwise entitled. You are not waiving any legal claims or rights because you are taking part in this study. If you do decide to take part, you are free to take back your consent and stop taking part at any time. If you stop, there is no penalty or loss of benefits to you.

K. Financial Responsibility
In the event that you suffer an injury as a direct result of the research procedures described above, emergency medical care required to treat the injury will be provided. No payment will be given by UCSD for any injury you may suffer as a direct result of the non-negligent performance of the procedures described above.

L. Agreement
This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions and have them answered. My decision to be in this study, to drop out of the study, or to refuse to answer any question, will not influence my present or future status as a patient, student, or employee at UCSD, or any other participating institution now or in the future. I will receive a copy of this consent form. My signature below shows that I am at least 18 years old and that I have chosen to take part in this research.

If you agree to be in this study, please sign your name below.

_____

Subject's signature

Witness to Consent Procedures*

Signature of Interviewer

Date

*Optional unless subject is illiterate, or unable to sign.

Note: Signed copied of this consent form must be a) retained on file by the Principal Investigator, and b) given to the participant