FORM APPROVED

OMB NO.: 0920-0840

EXPIRATION DATE: 2/28/2016

**Verbal Consent Form**

Attachment 5

Public reporting burden of this collection of information is estimated to average 5 minute per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; Attn: OMB-PRA (0920-0840)

**Informed Consent**

NORC at the University of Chicago

**Main Project Title:** Formative Research to Assess Injection Behaviors Among Young Persons Who Inject Drugs in Rural and Suburban Settings

**Principal Investigator:** David Rein, PhD

**Who is paying for this study?**

This research is supported by funding from the Centers for Disease Control and Prevention (CDC) Division of Viral Hepatitis.

**Who is doing this study?**

This research project is being carried out by NORC at the University of Chicago on behalf of the CDC.

**What we are asking you to do?**

For the purposes of this study, you will be asked to complete a 45-minute survey about injection drug use and to complete a blood test (a spot or two of blood is required) to find out if you have ever been infected with Hepatitis C (HCV). If you complete the survey and HCV test, you will receive $15 as a token of appreciation.

This consent form describes the procedures, risks and benefits of participation, and the steps we shall take to protect your confidentiality. The interviewer will be glad to answer any questions you might have. This process is called informed consent.

**A. Purpose of the Study.**

We are asking you to be in a research study. The purpose of this research is to examine the relationship between injection behaviors and Hepatitis C (HCV) among young people who inject drugs in suburban and rural settings. Additionally, this research will explore how young injectors’ social networks are connected with their risk for HCV. Young injector’s social networks may affect beliefs and behaviors about drug use as well as drug use practices, which in turn may affect the risk of HCV infection. The information we learn from this study will be used to develop programs to reduce the risk of HCV among young people who inject drugs. We are looking to enroll over 400 people into the study.

You are being asked to participate in this study because you:

* Are between the ages of 18 to 29;
* Have used a needle to inject street drugs within the past 12 months;
* Can complete a survey in English; and
* Have a photo ID with you.

**B. Procedures.**

The study will include one visit. This visit will be conducted at one of two syringe service program (SSP) locations. One location is the AIDS Resource Center of Wisconsin (ARCW) in Kenosha, WI. The other location is Bethany Place in Belleville, IL, which has both a fixed and a mobile site location.

At this visit, we will ask you to:

* Participate in a 45 minute survey.
  + In the survey, you will be asked questions about injection drug use, people in your social network, and your drug history.
* Collect a few drops of blood from your finger using a finger prick (this is called a “blood-spot”). Occasionally, we may need to prick your finger a second time in order to get enough blood.
  + Your blood will be tested for Hepatitis C (HCV).

To receive a token of appreciation for participation in this study, you must complete the survey and the HCV test.

Test results will be available within 20-40 minutes, usually before you have completed the survey. If you elect to receive the results of your lab tests, you will be referred to SSP staff who are trained and experienced in the delivery of test results to patients. If you are informed that you had a positive HCV test result, SSP staff will explain what HCV is, and refer you to a medical facility where you can obtain additional testing and receive follow-up care, if needed

**Coupon system**

At the end of the visit, you will be asked to distribute three coupons (or your coupon number) to other injection drug users who are 18-29 years of age. The purpose of the coupon or coupon number is to get other injection drug users to participate in the study. We will not ask people where they obtained the coupon or the coupon number.

**Results of tests for HCV**

The blood you provide (via blood spots) during your study visit will be used to help learn about HCV among young injection drug users. We will test the blood for HCV, will offer to tell you the results of your HCV test, and will provide a referral for follow-up testing and treatment, if necessary. You have the right to refuse to receive the test results, counseling, or referral.

**C. Risks and Discomforts.**

Some of the questions that we will ask you in the survey may make you feel uncomfortable. You can refuse to answer any question in the survey. In addition, we will ask you to recruit other people you already know for this study. Recruiting other people might make you feel uncomfortable or uneasy because of the nature of the study. You may decline to recruit other participants. You can still be in this study even if you do not want to recruit other people to be in the study.

Participation in the collection of the blood spots poses little risk. The procedures we will use to collect the blood samples are similar to those used in a doctor’s office and have been carefully designed to minimize any risk to you. However, while risks have been minimized, it is possible that you may experience some minor pain or bruising from the finger prick that we do to collect blood. If we don’t collect enough blood with the first finger prick, we may have to prick your finger a second time.

A NORC employee will take your blood spot. If the NORC employee mistakenly is stuck by a needle during the procedure to take your blood, the NORC employee will be transported to the nearest emergency department for care. You will be requested to accompany NORC staff to the emergency department for testing as deemed appropriate by emergency department staff.

**D. Benefits.**

By participating in this study, you will help researchers gain a better understanding of the injecting drug use practices of young people in suburban and rural areas, which may lead to better programs to reduce rates of HCV infection among this population. You will also receive a token of appreciation, which is explained below in Section F.

**E. Cost.**

There is no cost to you as a result of being in this research study, besides your time.

**F. Reimbursement.**

You will receive $15 as a token of appreciation (via reloadable electronic check card) at the completion of the survey and HCV test. You must complete the survey and the HCV test to receive the check card for your participation. In addition, coupons (or your coupon number) worth $10 will be provided to you for each referral to recruit a drug injecting peer. If the referred drug injecting peer participates and completes the study, your electronic check card will be loaded with the additional $10 token, up to a total of $30 (3 referrals). ***To receive the additional $10 for a referral, the person to whom you gave a coupon must be eligible for the study, and must complete the survey and the HCV test***.

The total amount possible to receive for participation is $45, $15 for your participation and $10 each for up to 3 people that you refer

**G. Confidentiality.**

You will not be identified in any report, publication, or presentation of this study or its results. No individual identifying information will be linked to your survey or test results. Data will only be analyzed for information on groups of people. We will keep your records confidential to the extent permitted by law. To protect your privacy, we will use the following procedures:

You will be randomly assigned a unique study identification number, based on your name and other random information. This code will be converted into an encrypted code called SHA-2 which will make it extremely difficult for anyone to convert the code back into your name. This code will only be used to ensure that you do not participate in the study more than one time. It will not be attached to your survey responses or your test results.

* We will not give any information about you to any of the people you refer into the study through the coupons you will receive at the end after you complete the survey and HCV test. The coupons will be tracked using a unique ID number. No identifying information about you or your recruit will be on the coupon.

**H. Certificate of Confidentiality**

To help us protect your privacy, we have obtained a Certificate of Confidentiality (CoC) from the Centers for Disease Control (CDC). With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings.

All answers that you give will be kept private. This means anything you tell us will not have to be given out to anyone, even if a court orders us to do so, unless you say it's okay. This protection does not extend to child abuse, elder abuse, or the possibility of serious harm to yourself or others. We will voluntarily report to the proper authorities suspected cases of child abuse, elder abuse, or if you tell us you are planning to cause serious harm to yourself or others.

As stated above, the protection offered by the CoC does not stop us from voluntarily reporting information about suspected or known sexual, physical, or other abuse of a child (anyone under age 18) or older person, or a subject’s threats of violence to self or others. If any member of the research team is given such information, he or she will make a report to the appropriate authorities.

The CoC cannot be used to resist a demand for information from personnel of the United States Government for audit or program evaluation purposes.

Even when a CoC is in place, you and your family members must still continue to actively protect your own privacy. If you voluntarily give your written consent for anyone to receive information about your participation in this research, then we may not use the CoC to withhold this information.

**I. Exceptions to Confidentiality.**

We will voluntarily alert the authorities if you tell us:

* Someone under age 18 is currently being physically or sexually abused by a caregiver; or
* An elder or dependent adult is currently being physically or sexually abused.

Should a report be filed on these grounds, no mention of your participation in this particular research project will be disclosed.

If you tell any member of the research team that you plan to harm yourself or others, we will contact a mental health professional. We will give only your name and why we feel you are at risk of harming yourself or others. We will also ask you for contact information to refer you to a mental health professional who will be able to provide you counseling or referrals to counseling. This report will not be linked to your survey information. You have the right to refuse to speak to the mental health professional. You may also request to speak to the mental health professional even if you do not express intent to harm yourself or others.

**J**. **Reporting Positive HCV Tests:**

If you choose to provide blood during the study visit, the sample will be tested for HCV. In compliance with Illinois state law, SSP staff must report positive HCV tests to the Illinois Department of Public Health (IDPH). The IDPH keeps track of all positive HCV tests. The state of Illinois allows anonymous reporting, so we will not have to report your name or other identifying information to the state health department if you have a positive HCV test result. State law in Wisconsin does not require the reporting of HCV test results.

**K. Offer to Answer Questions:**

If you have a question about your rights as a research participant, or feel you have been harmed as a result of participating in the study, you may contact the NORC Institutional Review Board (IRB) by toll-free telephone number at (866) 309-0542.

You will be given a copy of this form to keep. Please note that you are personally responsible for protecting your identity as a participant in this study by either destroying or placing this consent form in a secure place.

**L. Voluntary Participation**

Your participation in this study is voluntary. You do not have to answer any questions that you do not wish to answer and you can stop the survey at any time. If you decide to be in this study, you are free to change your mind and withdraw at any time. If you decide that you no longer wish to participate in this study, no future data will be collected from you. **However, all data we have collected from you up to that time, including your survey answers and blood samples, will be kept by the research team** .

**M. Agreement**

I have read (or someone has read to me) the information provided above. I have been given the chance to ask questions and all of my questions have been answered to my satisfaction. I understand that my participation in this study is entirely voluntary. I understand that I may leave the study at any point. My verbal consent to the NORC Field Staff means that I have chosen to take part in this research.

Verbal Consent Obtained (Field Staff):

Yes

No

Agree to complete survey and HCV test (Participant):

Yes

No

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Name of Field Staff Signature Date