University of California, San Diego (UCSD)
Consent to Act as a Research Subject

"STAHR" Study To Assess Hepatitis C Risk among Young Adult Injection Drug Users in San Diego

PURPOSE OF STUDY

Dr. Richard Garfein and his colleagues from UCSD and the Centers for Disease Control and Prevention (CDC) in Atlanta are doing a research study. The study will look at how young people who inject drugs get infected with Hepatitis C virus (HCV, a virus that can harm the liver) and HIV (the virus that causes AIDS). The results of this study may lead to new programs to help prevent the spread of HCV and HIV.

You are being asked to be part of this study because you are between 18 and 30 years old and have told us that you inject drugs. About 1,000 people will be part of this study over the next year.

Joining this study is voluntary. The details below will help you make an informed choice about joining or not joining the study. You may have received a coupon about the study. 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 join the study only if you want to. Do not take part the study because someone else wants you to.

PROCEDURES

If you choose to be in the study, you will be asked to do the following:

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 about your health, sex life, and drug use. You will fill out the survey on a computer. To protect your privacy, a study ID number will be entered into the computer instead of your name. No one will watch how you answer the survey. A staff member will show you how to use the computer. The staff member will help if you have problems, but will not watch you fill-in the survey. The survey takes about 55 minutes to finish. You may skip any question you don't want to answer. You can stop the survey at any time.

3. After the survey, a trained staff counselor will explain the HCV and HIV tests. The counselor will discuss what the results could mean to you. The counseling will take about 15-20 minutes. The counselor will also talk to you about how you may feel about your results. The counselor will discuss how you can avoid getting or spreading HCV and HIV. You will be given information and advice about drug treatment, as well as safer drug use and sex practices. This information can help you avoid getting or giving HCV and HIV to others. You can ask questions about your health. The counselor will offer you free condoms and bleach kits. Counseling sessions may be observed by the project directors to see how the counselors are

doing. You may refuse to let a project director observe your counseling session. The counselor will also tell you about a vaccine (shots) that can protect you against other viruses that can harm your liver (hepatitis A and hepatitis B) and places where you can get them. The vaccine is given in 3 shots over 6 months. We will try to refer you to a clinic where the shots are free, but we cannot insure that the clinics will always be able to give them for free. We will also look at the willingness of young people who inject drugs to get these shots. If you choose to get these shots, we will ask you to tell us each time you get one.

4. We will also ask you for contact information. This information will help us reach you if you miss the visit for your test results. If you do not come back for your test results, we will try at least 3 times to contact you using the information you give us. We will never give your test results to anyone other than you without your written permission.

5. **Three** tubes, about 1.5 tablespoons, of blood will be drawn from one of your veins. It will be tested to look for HCV and HIV antibodies.

6. If you agree, we also run tests that tell us if you were recently infected with HCV and HIV. A test called NAT can see if you have the HCV or HIV virus in your blood before an antibody test can. The NAT test is routinely used for people who donate blood. It is also used to diagnose people with HIV. If your blood tests positive for HIV, we will do a second test called the Less Sensitive test. This antibody test will tell us if you were infected with HIV in the last 6 months. There is no Less Sensitive test for HCV. If this test is positive, we will want you to know the results quickly. Therefore, we will try to contact you before your next visit if these tests show you have a new HCV or HIV infection. All tests are for research use only. We will give you the results of the tests, but if the tests suggest that you have been infected with HIV or HCV, you will be referred to a clinic where you can have your results confirmed for medical use.

You agree to have your blood tested for new HCV and HIV infections.

Yes No Initials_____

7. If you agree, the research team would like to freeze and store some of your blood. The samples will be stored at the CDC in Atlanta. Future studies might use your samples and other study data, but not your name. Future tests will only include standard tests for HCV, HIV or other infections that may be spread through sex or injecting illegal drugs. For example, if you are found to be infected, there might be a new test that will tell us more about your type of HCV or HIV. Tests may also tell us how long ago you got infected. Genetic testing may be done on the viruses in your blood, but not on your own DNA. Your blood will not be used for cloning. To guard your privacy, we will use your study ID number instead of your name on the blood tubes. Six months after the study ends, we will destroy the link between your name and study ID number. After that time, we will not be able to tell which samples belonged to you and therefore will not be able to give you the results of future tests. Your blood will be stored for up to 50 years. Anyone that may receive these samples will be partners in this study. You can still be in this study even if you do not want your blood to be stored for future studies.

You agree to storage of your blood at the CDC in Atlanta to be used for future testing.

Yes No Initials_____

If you agree to storage of your blood now, but change your mind before the link between your name and study ID number is destroyed 6 months after the study ends, you may withdraw you consent for storage. However, after that time, it will be impossible to discard your samples. To withdraw your consent for testing of stored blood, contact Jazmine Cuevas, Project Coordinator at (619) 543-5010.

8. After your blood is drawn, you will be asked to come back in 2-3 weeks for your HCV and HIV test results. If you do not want your test results, you do not have to come back for this visit. At that time, you will meet with a counselor face-to-face for about 20 minutes to learn your results and what they mean to you. A counselor will talk to you about how to keep from getting or spreading HCV and HIV. If you are infected, the counselor will help you make an appointment in one of the local health care clinics to get retesting and medical care for HCV or HIV infection. The counselor can give you information about drug treatment and advice about safer drug use and sex practices. You can ask questions about your health. The counselor will offer you free condoms and bleach kits. These sessions may be observed to allow project supervisors see how the counselors are doing. You will also be reminded about hepatitis A and hepatitis B vaccinations. Also, the counselor will talk to you about where you can get medical care and other services if you need them.

9. Some participants may be given up to 3 coupons to invite people they know into the study. The coupons tell people where they can learn more about this study. Coupons must be turned in to be part of the study. Each coupon has a unique number on it. This number will be linked to your study ID so we can compensate you for each qualified person you refer. Not everyone will receive these coupons.

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

You agree to be told about other research studies.

Yes No Initials_____

This study is not able to give treatment for medical conditions. But if you allow us, project staff will refer you to your personal doctor or health care and support services. All tests done by this study are for research purposes only and should not be used for making decisions about your care. For this reason, when you receive your results, the counselor will advise you on where you can get retested for clinical purposes.

<u>RISKS/DISCOMFORTS</u>

There are some possible risks and discomforts to you from participating in this study. These are listed below.

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 can skip them. Also, you can stop the survey or withdraw from the study at any time.

2. You may feel pain or discomfort from the needle when your blood is drawn. There is a slight risk of bruising, fainting, dizziness, lightheadedness and infection from the blood draw. The person who draws your blood is 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.

3. You may learn that you have HCV and/or HIV. This may cause you to feel afraid, angry or sad. A counselor will be available to talk with you about these feelings.

4. 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. We cannot ensure complete privacy. We will give you an ID number to protect your privacy. We will use the ID number instead of your name on the computer survey and blood samples to protect your answers and test results.

BENEFITS

As a benefit of this study you may learn your HCV and HIV test results. Learning that you are negative may motivate you to protect yourself from becoming infected, and study staff can give you advice on how to avoid getting infected in the future. Learning that you are infected with HCV or HIV may also result in some benefits that include the early start of treatment and taking steps to prevent others from becoming infected by you. You will be referred to a local hospital and other local groups for health services and support if you have HCV or HIV.

Whether you join this study or not, you may ask the study staff for information about drug treatment programs or other resources that you may desire. Our staff will offer you the chance to receive a referral for drug treatment and give you advice about drug use and safer sex. You will be able to ask questions about your health during counseling sessions. You will also be told where you can get free vaccine (shots) that protect against hepatitis A and B.

By taking part in this study, you may be helping researchers to learn more about HCV and HIV and ways to prevent people in your community from getting hepatitis C or AIDS. Results from this study will be available to doctors and scientists and may help them to give better care to others like you. At no time will individual test results or survey answers be given to persons outside the study without your written consent.

ALTERNATIVES TO BEING IN THE STUDY

You do not have to be part of this study. If you choose not to be part of this study, it will have no effect on your care or employment at UCSD or the UCSD Medical Center.

INCENTIVES

You will be paid $25 to thank you for your participation and to cover any expenses you might have incurred for taking part in the study.

As an incentive for returning for the HCV and HIV test results we offer $10. As an incentive for returning to verify that you received a hepatitis vaccination we will pay you $5 each time (up to 3 times) you bring us a record showing that you received a dose of hepatitis A/B vaccine.

If you are given recruitment coupons, you will receive $10 for each person you refer to the study that is qualified to join. 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, a current drug injector, and not already in the study. Only one person can be referred with each coupon. Only one-quarter of the people in this study will be given recruitment coupons.

CONFIDENTIALITY

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. If you tell us you are planning to cause serious harm to yourself or others, we must report that too. 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 study visit or give you information that is important to your health. Your name and address will be kept separate from the survey data and test results. Only a paper log and a computer file will link your name and unique ID number. This log will be kept in a locked file drawer at the study office and the computer file will be password protected on the project coordinators computer. You will not be allowed to be in this study more than once. Only the principal investigator and senior project staff will have access to study files. The paper log and computer file will be destroyed 6 months after the end of the study making it impossible for anyone to know which data came from you. The information from this study may be published in scientific journals or presented at scientific meetings, but your name will not be included. Your identity will be kept strictly confidential.

RESEARCH-RELATED INJURY

If you are injured as a direct result of participation in this research, the University of California will provide any medical care you need to treat those injuries. The University will not provide any other form of compensation to you if you are injured. You may call the Human Research Protections Program Office at (858) 455-5050 for more information about this, to inquire about your rights as a research subject or to report research-related problems.

Dr. Richard Garfein 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 (619)543-5010.

VOLUNTARY PARTICIPATION & WITHDRAWAL STATEMENT

You are taking part in this research study on a voluntary basis. Your choice of whether or not to take part will not interfere with your right to health care or benefits 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 decide to take part, you are free to take back your consent and stop being part of they study at any time. If you stop, there is no penalty or loss of benefits to you.

The researchers may also withdraw you from the study at any time. This could happen if you are unable or unwilling to complete the computer survey, or you behave in a threatening or disruptive way.

Dr. Garfein and/or _____ has explained this study to you and answered your questions. If you have other questions or research-related problems, you may reach Dr. Garfein at 858-822-3018. You volunteer to take part in this research. You have had a chance to ask questions and have them answered. Your 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. You have received an unsigned copy of this consent form to keep for your records. You have also received a copy of "The Experimental Subject's Bill of Rights" to keep. Your signature below shows that you are at least 18 years old and that you chose to be part of this study.

You agree to participate:

_____
Printed Name

_____ _____
Signature Date

_____ _____
Witness to Consent Procedures* Date

_____ _____
Project Staff Signature Date

_____
Date

*Only if subject is illiterate, or unable to sign.