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Study to Assess Hepatitis Risk

Attachment 6

Informed Consent Forms

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Form Approved:
OMB #: 0920-XXXX
Expiration Date

STUDY TO ASSESS HCV RISK
(STAHR)
INFORMED CONSENT

Flesch-Kincaid Grade Level = 7.5

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 hepatitis C virus (HCV, a virus that can harm the liver) and HIV (the virus that causes AIDS) 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 HCV and HIV 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. You may have received a coupon inviting you to participate. 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 55 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 and 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.

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3. After the survey, you will get pre-test counseling and have your blood drawn for HCV and HIV 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/she will also talk to you about the effect of getting your results. You will be told how to avoid getting or spreading HCV or HIV. 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. This will allow project directors to 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 HCV and HIV. In addition to the blood drawing from your veins, you will be also asked to provide a drop of blood by a finger prick for HIV rapid testing.

5. 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. Your samples might be used for future studies and they would be linked to the other data about you collected in this study. Future tests will be limited to standard tests for HCV or other infections that may be spread through injecting drug use. For example, if you are found to be infected there might be a new test that will tell us more about the type of HCV you have or how long ago you were infected. Your sample will not be used for any genetic testing. Your blood will not be used for cloning or commercial purposes. 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. 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 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 be asked to come back within 2-3 weeks for your HCV and HIV 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 HCV or HIV. He/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 bleach and condoms. 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

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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. You **may** be given 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 study. 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. Not everyone will receive these coupons.

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.

I give permission for the researchers to ask me to participate in other studies in the future.

Yes_____ No_____ _____
Signature

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. 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.

3. 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.

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.

D. Benefits

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

1. You will be counseled about risk and how to prevent HCV and HIV infection. Sexually transmitted diseases and other health problems that can come from using drugs will also be covered. 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.

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2. You will get free HCV and HIV 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 HCV or HIV.

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 HCV, HIV 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 ID 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. Only to the principal investigator or senior project staff will have access. This file will be destroyed 6 months after the study ends. Only study staff with a need for access will have 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 for taking part in this study. You will get $10 when you come back for the HCV and HIV test results. You will also get $5 each time (up to 3) that you bring us a record showing that you received a dose of hepatitis A/B vaccine.

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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.

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Subject's signature

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Witness to Consent Procedures*

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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