The University of New Mexico Health Sciences Center
Consent to Participate in Research

Hepatitis: Treatment and Integrated Prevention (H-TIPS)

03/12/2015

Introduction

You are being asked to participate in a research study that is being done by Kimberly Page, PhD, who is the Principal Investigator and her partners, from the Department of Epidemiology. This research is to study how often people become infected with the hepatitis C virus (HCV), what their risk factors are and if there are any benefits from extra care.

The purpose of this study is to look at the rate of HCV diagnosis and if that rate is changed by a management program.

You are being asked to participate in this study because you have a history of injection drug use. At least 338 people will be enrolled into this study at the University of New Mexico.

This study is funded by the U.S. Centers for Disease Control (CDC) and Prevention.

This form will explain the research study, and the possible risks and benefits to you. We encourage you to talk with your family and friends before you decide to participate in this research study. If you have any questions, please ask one of the study investigators.

What will happen if I decide to participate?

After you have gone through the consent process and signed the consent form, we will test your blood for HCV and the hepatitis B virus (HBV). You can also be tested for Human Immunodeficiency Virus (HIV) if you want. Then, we will interview you (using a questionnaire) to find out more about you, like your background and injection drug use history. You will need to return to the clinic van in two weeks so that we may provide you with the results.

We will also use a digital fingerprint technology to identify you for research purposes only.

If your blood test results show that you have been exposed to HCV, the following things will happen:

- You will have a one-on-one education session with a member of the study staff, that will cover 1) what HCV does to your body, 2) how to reduce the risk of spreading HCV, 3) things you can do to keep your liver healthy, and 4) the current treatments available.
- You will be referred for standard HCV care
- You will have follow up HCV testing

Depending on which region you live in (Northeast or Southwest New Mexico), you may also be in a treatment management group, which means that you will get payments if you go to your treatment appointments. This is described below in the payment section. The study does not pay for your treatment, it only gives you referrals for where to go for treatment.

If you test negative for HCV exposure, we will give you referrals for prevention services as well as addiction and behavioral care. You will also have a follow up HCV test every 3 months for one year. At months 3 and 9, if you want, you can have anti-HCV testing and blood collection for future HCV RNA testing. At months 6 and 12, your visit will include a survey and blood tests.

All blood samples will be identified with only your participant ID number to keep your personal information confidential. The participant ID number is a number created by scanning your fingerprint. This number will be assigned to you and only you so that we can keep all of your information together without having to identify you. Your fingerprint will only be used to create this number and will not be used for anything else. We will not save a copy of your fingerprint. A sample will be stored in a secure lab facility at the University of New Mexico for five years to do comparison testing if you become re-infected with HCV while you are part of the study.

How long will I be in this study?

You will be in the study for one year. There will be up to 6 visits with study staff, for up to a total of 24 hours over the entire year.

Visit	Procedure	
	Baseline Interview	1st visit
1	Anti-HCV Test and Blood Draw for RNA	1st visit
1.1	HCV RNA Results	1 week after 1st visit
2	3 Month Check In (Optional Anti-HCV testing)	3 months after 1st visit
3	6 Month Follow Up Visit with Interview and HCV Testing	6 months after 1st visit
4	9 Month Check In (Optional Anti-HCV Testing)	9 months after 1st visit
5	12 Month Follow Up Visit with Interview and HCV Testing and Results	1 year after 1st visit

What are the risks or side effects of being in this study?

There are risks of stress, emotional distress, inconvenience and possible loss of privacy and confidentiality associated with participating in a research study.

Being tested for HCV, HIV and HBV may cause anxiety about test results, whether they are positive or negative.

Risks relating to blood draws include: bruising, discomfort and possible infection.

For more information about risks and side effects, ask the investigator.

What are the benefits to being in this study?

You will be able to know for sure if you have been exposed to HCV if you participate in this study. You may benefit from HCV risk reduction counseling as well as from referrals or linkage to medical care. The information you provide may help health professionals and researchers better understand and prevent HCV infection in young drug users. You

will also have the chance to learn your HIV and HBV status and receive additional risk reduction counseling, referrals and linkage to medical care if you are interested.

What other choices do I have if I do not want to be in this study?

You do not have to be in this study. If you choose not to be in this study, we can refer you to other providers in the area that offer harm reduction services, HIV/HBV/HCV testing and referrals. You should discuss all available options with your doctor.

How will my information be kept confidential?

We will take measures to protect the security of all your personal information, but we cannot guarantee confidentiality of all study data.

Information in your study records is used by study staff and, in some cases it will be shared with the CDC who sponsors the study. The University of New Mexico Health Sciences Center Human Research Review Committee (HRRC) that oversees human subject research and the United States Centers for Disease Control and Prevention, and/or other organizations may be allowed to access your records. There may be times when we are required by law to share your information. If you get the Twinrix® vaccine we are required by New Mexico law to enter that information into the New Mexico Department of Health Immunization Registry, a confidential database. If you test positive for HIV, HBV or HCV, we are required by law to report this to the Department of Health. You may be contacted by them. They are required to keep your information confidential. Your name will not be used in any published reports about this study.

To help us protect your privacy, we have received a Certificate of Confidentiality from the National Institutes of Health (NIH). With this Certificate, the researchers cannot be forced to release information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects, like this study, or for information that must be released in order to meet the requirements of the NIH.

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If any person or agency gets your written consent to receive research information, then the researchers may not use the Certificate to refuse to give that information. The researchers will not share any of your answers to the interview or any of your test results with anyone.

The Certificate of Confidentiality does not prevent the researchers from reporting without your consent, information that would identify you as a participant in the research project if you tell us about matters that must be legally reported such as child and elder abuse, sexual abuse, or wanting to harm yourself or others. We may need to report this to local law authorities to keep that person safe.

In this study you will be asked about drug use and other possibly illegal activities. Upon consent, you will be asked to provide contact information so that research staff can remind you to come back for appointments in case you forget. The researchers and staff will keep information about you as confidential as possible, but complete confidentiality cannot be guaranteed. Your blood samples and interview will be labeled with a study ID code and date of birth only. Your interview will be kept in a locked file and only Dr. Page and her co-investigators will have access to it. Therefore, no one will be able to connect blood samples or answers you give in the interview back to you. No information that might identify you will be used in any reports or publications that may result from this study.

A copy of this consent form will be kept in your medical record.

HIPAA Authorization for Use and Disclosure of Your Protected Health Information (HIPAA)

As a part of this study, we will be collecting health information about you. This information is "protected" because it is identifiable or "linked" to you.

Protected Health Information (PHI)

By signing this consent document, you are allowing the investigators and other authorized personnel to use your protected health information for the purposes of this study. This information may include: medical history, previous and/or current treatments, laboratory tests, general health status and medical record number. By signing the medical release form, you are authorizing the study staff to contact your

treatment providers to check your treatment and attendance at appointments. This information will be used only for study purposes.

Right to Withdraw Your Authorization

Your authorization for the use of your health information for this study shall not expire unless you cancel this authorization. Your health information will be used as long as it is needed for this study. However, you may withdraw your authorization at any time if you notify the research team in writing. Please know that the research team will not have to destroy or retrieve any of your health information that has already been used before your withdrawal is received.

Refusal to Sign

If you choose not to sign this consent form and authorization for the use and disclosure of your PHI, you will not be allowed to take part in the research study.

What are the costs of taking part in this study?

There will be no costs to you as a result of participating in this study.

What will happen if I am injured or become sick because I took part in this study?

If you have an injury or illness that is caused by your participation in this study, reimbursement for all related costs of care will be sought from your insurer, managed care plan, or other benefits program. If you do not have insurance, you may be responsible for these costs. You will also be responsible for any associated co-payments or deductibles required by your insurance.

It is important for you to tell the investigator immediately if you have been injured or become sick because of taking part in this study. If you have any questions about these issues, or believe that you have been treated carelessly in the study, please contact the Human Research Review Committee (HRRC) at the University of New Mexico Health Sciences Center, Albuquerque, New Mexico 87131, (505) 272-1129 for more information.

Will I be paid for taking part in this study?

If you test positive for the HCV test, you may receive up to $105 (Region 1 - Northwest NM) or $35 (Region 2 - Southwest NM) as shown by the table below. If you are in

Region 1, you will receive a pre-paid debit card at the end of Visit 1 with $25 for the first visit, and then the rest of the payments will be loaded onto the card after each visit, once it has been confirmed that you completed each visit. If you are in Region 2, you will receive payment in cash at the end of Visits 1 and 9.

Visit		Region 1	Region 2
1	HCV Infection education session	$25	$25
2	Initial Assessment	$5	0
3	Laboratory Visit	$5	0
4	Follow Up Assessment #1	$5	0
	If receiving HCV treatment:		
5	HCV Treatment Follow Up Week 2	$10	0
6	HCV Treatment Follow Up Week 4	$10	0
7	HCV Treatment Follow Up Week 8	$10	0
8	HCV Treatment Follow Up Week 12	$15	0
9	12 Months HCV Results	$10	$10
TOTAL		$105	$35

If you test negative for the HCV test, you may receive up to $60 according to the table below. You will receive payment in cash in the amount listed below at the end of each visit.

Visit	Procedure	Amount
	Baseline Interview	$10
1	Anti-HCV Test and Blood Draw for RNA	$5
1.1	HCV RNA Results	$15
2	3 Month Check In	$5

	(Optional Anti-HCV testing)	
3	6 Month Follow Up Visit with Interview and HCV Testing	$10
4	9 Month Check In (Optional Anti-HCV Testing)	$5
5	12 Month Follow Up Visit with Interview and HCV Testing and Results	$10
TOTAL		$60

How will I know if you learn something new that may change my mind about participating?

You will be informed of any significant new findings that become available during the course of the study, such as changes in the risks or benefits resulting from participating in the research or new alternatives to participation that might change your mind about participating.

Can I stop being in the study once I begin?

Your participation in this study is completely voluntary. You have the right to choose not to participate or to withdraw your participation from the study at any time during the study. If you withdraw you are entitled to keep anything that you have received from the study, including all compensation that you have received. After withdrawing, you will no long receive any further compensation. The study has the right to keep all data samples that you have provided while you were a part of the study. Withdrawing from the study will not affect your future health care or other services that you are entitled to.

Your study doctor may also withdraw you from the study if participating is no longer in your health's best interest or for noncompliance with study related activities/visits.

Whom can I call with questions or complaints about this study?

If you have any questions, concerns or complaints at any time about the research study, Kimberly Page, PhD, or her associates will be glad to answer them at (505) 272-2520.

If you would like to speak with someone other than the research team, you may call the UNMHSC HRRC at (505) 272-1129.

Whom can I call with questions about my rights as a research participant?

If you have questions regarding your rights as a research participant, you may call the UNMHSC HRRC at (505) 272-1129. The HRRC is a group of people from UNM and the community who provide independent oversight of safety and ethical issues related to research involving human participants. For more information, you may also access the HRRC website at http://hsc.unm.edu/som/research/hrrc/.

CONSENT

You are making a decision whether to participate in this study. Your signature below indicates that you read the information provided (or the information was read to you). By signing this consent form, you are not waiving any of your legal rights as a research participant.

I have had an opportunity to ask questions and all questions have been answered to my satisfaction. By signing this consent form, I agree to participate in this study. A copy of this consent form will be provided to you.

_____ _____ _____

Name of Adult Subject (print) Signature of Adult Subject Date

INVESTIGATOR SIGNATURE

I have explained the research to the participant and answered all of his/her questions. I believe that he/she understands the information described in this consent form and freely consents to participate.

_____

Name of Investigator/ Research Team Member (type or print)

_____ _____

(Signature of Investigator/ Research Team Member) Date