UNIVERSITY OF CINCINNATI - Medical
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: Southern Ohio Prevents Hepatitis (StOPHeP)

UC IRB Study #: 2014-7919

Sponsor Name: Centers for Disease Control and Prevention

Investigator Information:

Judith Feinberg MD (513) 584-6977

Principal Investigator Name Telephone Number 24 hr Emergency Contact

Subject Name: _____ Date of Birth: _____/_____/____

INTRODUCTION:
Hepatitis C is a virus that infects the liver. About 80% of people who get hepatitis C will go on to develop a chronic infection. Untreated chronic hepatitis C can cause severe liver damage (cirrhosis) and liver failure years after infection. Once liver failure occurs, the only treatment is a liver transplant. Hepatitis C is easily spread by sharing infected blood that can be inside a needle, syringe or the "works" (cotton, cooker) used to inject drugs. Hepatitis C, associated with injecting drugs, has reached epidemic proportions in southern Ohio and nearby Kentucky and West Virginia.

Before you agree to participate in this research study, it is important that you be told the purpose, procedures, benefits, risks, discomforts, and precautions of the research. You should also be told what alternative procedures are available to you if you do not participate in the research study. The informed consent document is a written summary of this information. Be sure to ask questions while you read this consent document and ask questions if there is anything that you do not understand.

WHY IS THIS RESEARCH BEING DONE?
A biomedical or health-related research study is performed to answer specific questions about a disease. ***The purpose of this research study is to learn about the injection practices and health of people who inject drugs (PWID), including possible risk factors for hepatitis C (hep C).***

WHY HAVE YOU BEEN ASKED TO TAKE PART IN THIS RESEARCH STUDY?
You are being asked to take part in this research study because you are between 18 and 30 years old and have injected drugs within the past year. You must speak and understand English. You must live in a suburban or rural county in one of 21 southern Ohio counties (excluding Hamilton County), or a county in Kentucky or West Virginia that borders Ohio. If you live in Kentucky or West Virginia, you must be willing to travel to one of the study sites in southern Ohio.

WHAT ARE YOUR RIGHTS AS A PARTICIPANT?

You may choose either to take part or not to take part in this research study. If you decide to take part, you may decide to leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to you.

The investigators will tell you about new information that may affect your health, welfare, or willingness to stay in this study. If you withdraw from the study, you will be asked to give a last blood sample. This is for your safety in case you have become infected with hep C since your previous study blood test.

If you have questions about the study, you will have a chance to talk to one of the study staff or your regular doctor. Do not sign this form unless you have had the chance to ask questions and have received satisfactory answers.

HOW LONG WILL YOU BE IN THE RESEARCH STUDY?

You will be in the research study for approximately 1 year. If you **do not** have hep C, we want to find out if we can help you avoid getting it. If you **already have hep C**, we want to find out if we can help you from giving it to others in your life, connect you with care for your hep C if you are interested, and avoid reinfection.

WHO IS CONDUCTING THE RESEARCH STUDY?

This study is sponsored by the U.S. Centers for Disease Control and Prevention (CDC). The study is directed by Dr. Judith Feinberg, the researcher at the University of Cincinnati and the Medical Director of the Cincinnati Exchange Project. Dr. Feinberg is an expert in infectious diseases, including hep C. She will be one of the hep C specialists that you may be referred to for care if you are interested, although hep C care is not a part of this study.

HOW MANY PEOPLE WILL TAKE PART IN THE RESEARCH STUDY?

A total of 400 people will take part in this study by enrolling at a recruitment site located in southern Ohio. The recruitment sites are located at the Cincinnati Exchange Project, City of Portsmouth Health Department syringe exchange program, Northland Treatment Center, and Health Recovery Services.

WHAT IS INVOLVED IN THE RESEARCH STUDY?

Study staff, called Peer Navigators (PN), will explain the study to you in detail and will review this consent form page by page. You will complete a questionnaire about your health and your injection history that will take about 60-90 minutes. At enrollment, you will have 2 tubes of venous blood taken for testing for viral hepatitis and HIV. Blood from one tube will be frozen and stored for possible future testing.

There will be a total of 5 study visits: the enrollment visit and 4 brief follow-up visits at 3, 6, 9 and 12 months for a blood draw and a brief survey. Over the course of the one-year study period a total of 10 tubes of blood (2 tubes per visit), totaling approximately 5 tablespoons, will be taken for virologic testing.

The PN will ask you the best way to stay in contact. You will also be asked to provide contact information for at least 2 people who will know how to get in touch with you. The PN's contact information will be provided to you and you will be able to call, text, or email your PN. You will be asked to participate in an online closed social network that is only available to people in the study. You will be given information on how to protect your privacy online. Through the enrollment process, phone contact and the StOPHeP social network, the PN will make sure that you know all about hep C—symptoms, blood tests, treatment, access to medical care, how to prevent getting hep C, and how to

prevent giving it to someone else. Referrals to drug treatment programs and other services will also be available from your PN. We will track the kinds of services you are offered and which ones you take advantage of, as well as reasons that you may not receive services.

If you have chronic hep C and are interested in hep C care, your PN can refer you to a doctor who is experienced in managing hep C. If you do not have health insurance, your PN will assist you with obtaining it. The actual care for hep C is not covered by the study. You will be asked to sign a Release of Information form so that we can get the results of your hep C care. This would include the name of any medications you are given for hep C and the results of treatment (cured, or not cured).

You will be asked to refer at least 3 people with whom you have injected drugs and/or have an intimate relationship with to see if they want to be in the study. You will receive a $10 gift card for each person you refer that joins the study.

Your PN or other study staff may contact you by phone, text, email or letter. Your blood test results will not be given to you by email or through the closed social network. You will only get test results in person, by phone or text, or by letter.

WHAT ARE THE RISKS AND DISCOMFORTS OF THE RESEARCH STUDY?

The risks of study participation are minimal and are mostly associated with disclosure of your personal information. However, extensive procedures are in place to limit those risks. All University of Cincinnati (UC) employees sign data confidentiality agreements as part of the hiring process. They follow detailed written operational procedures for the handling of research data. Employees who do not follow these procedures are fired. All study data will be kept in password-protected computer files and paper files will be stored in a locked file cabinet within a locked office at UC that is accessible only by study personnel. Only study staff will have access to this information. Drawing blood from a vein may cause some discomfort, bleeding or bruising at the site. Rarely, fainting or infection may occur.

ARE THERE BENEFITS TO TAKING PART IN THE RESEARCH STUDY?

The researcher and sponsor of this study do not promise that you will receive any benefits from this study. The information learned from this research study will benefit other people in the future who inject drugs and who either have chronic hep C or who can avoid getting infected with hep C. Potential benefits to you may include: knowledge of your hep B, hep C and HIV status; referral to medical care for chronic infection with hepatitis and/or HIV; learning how to prevent the spread of hep C to others if you are infected; or learning how to avoid getting hep C infection if you do not have it.

WHAT OTHER CHOICES FOR CARE ARE THERE?

You do not need to be in this study to be tested for hep B, hep C and HIV, or to be referred for medical care, hep C care or drug treatment. It is important for your welfare for you to know whether or not you have hep C. Hep C can now be cured in most cases with pills taken by mouth for 12-24 weeks, depending on the strain of hep C.

WHAT ARE YOUR COSTS TO BE IN THIS STUDY?

The only cost that you will be responsible for is travel to the study site (5 visits over 12 months). The gift card you receive at each visit can help with this. Your PN will assist with referrals to general medical care and other services, but the cost of this care is not covered by the study and must be covered by health insurance or other forms of payment.

WILL YOU BE PAID TO PARTICIPATE IN THIS RESEARCH STUDY?

You will be given a $10 gift card at each study visit (a total of $50 over 1 year) in appreciation for your time and effort. Additionally, you will also receive a $10 gift card for each person that you refer who also enrolls in the study. The maximum amount that you can receive for referring people to the study is $30. You will not be reimbursed for your time and effort for remaining visits if you leave the study early.

If you receive payments for being a part of this research study, you may be asked to complete an Internal Revenue Service (IRS) form. The amount you receive may count as income and may affect your income taxes. Your social security number will be required to complete the IRS form.

WHAT IS A CERTIFICATE OF CONFIDENTIALITY?

To further protect your privacy, the researchers have obtained a Certificate of Confidentiality from the U.S. Department of Health and Human Services (DHHS). With this certificate, the researchers may not be forced to disclose information about you in court. Disclosure may be necessary, however, upon request of DHHS for program evaluation purposes.

A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research.

Even with the Certificate of Confidentiality, if the investigator learns about abuse of a child or elderly person or that you intend to harm yourself or someone else, or about certain communicable diseases, they will report that to the proper authorities. If keeping information private would immediately put you or someone else in danger, the researchers would release information to protect you or another person.

AVAILABILITY OF INFORMATION

If you choose to participate in this study, you will receive a signed and dated copy of this consent form. You will be told about any new information from this or other studies that may affect your health, welfare, or willingness to stay in this study.

Like most web-based services, Ning automatically receives and records information on our server logs from their browser when using the Ning platform (this includes the IP address at the time of registration). Methods such as clear GIFs and “cookies” may be used to collect this information. Information collected may include: IP address, Ning cookie information, unique device or ID, browser type, and content or pages accessed from the Ning platform. For more information about Ning privacy policy please visit: http://www.ning.com/privacy/.

HOW WILL INFORMATION ABOUT YOU BE KEPT PRIVATE AND CONFIDENTIAL?

Every effort will be made to maintain the confidentiality of your medical and research records related to this study. Agents of the United States Centers for Disease Control and Prevention (the study sponsor) and the University of Cincinnati Institutional Review Board (IRB), and other regulatory authorities will be granted direct access to your original medical and research records for verification of research study procedures or study data without violating your confidentiality, to the extent permitted by the applicable laws and regulations. By signing this consent form, you or your legally authorized representative is authorizing such access. The data from the study may be published; however, you will not be identified by name. Your identity will remain confidential unless disclosure is required by law.

AUTHORIZATION TO USE AND DISCLOSE HEALTH INFORMATION

A federal regulation known as the Privacy Rule gives you certain rights concerning the privacy of your health information. Researchers covered by this regulation are required to get your authorization (permission) to use and disclose (share with others) any health information that could identify you.

If you sign this informed consent form, you are giving permission for the use and disclosure of your health information for purposes of this research study. You do not have to give this permission. Your health care outside of the study, payment for your health care, and your health care benefits will not be affected if you choose not to sign this form. However, if you do not sign this form, you will not be able to participate in the study.

WHO WILL USE AND DISCLOSE MY HEALTH INFORMATION?

The study doctor and research staff may use your health information to conduct, review, and determine the results of the study. The study team may also use your information to prepare reports or publications about the study. However, your name will not appear in any report or publication.

WHAT HEALTH INFORMATION WILL BE USED AND DISCLOSED?

The study team will record your medical and drug use history, the treatment you receive, and the results of tests done during the study on study forms. Representatives from the groups identified below may need to look at your medical records to make sure that the information on the study forms is correct or that the study was conducted properly. Your medical records may include other health information about you and may include documents that directly identify you. Reviews like that will take place at the study center or where the medical records are stored and can take place after the study is over.

WHO WILL RECEIVE MY HEALTH INFORMATION?

Your study information or medical records (as described above) or both may be shared with the following people or groups:

- The U.S. Centers for Disease Control and Prevention, the study sponsor
- Researchers who are conducting this study
- UC Institutional Review Board and any other committees responsible for overseeing the research
- Staff of the UC Human Research Protection Program

WILL MY INFORMATION BE PROTECTED BY THE PRIVACY RULE AFTER IT IS DISCLOSED TO OTHERS?

UC Health, the Cincinnati Exchange Project, the Portsmouth City Department of Health, Northland Treatment Center, and Health Recovery Services are required by the Privacy Rule to protect your health information. After your information is shared with others, such as the study sponsor, it may no longer be protected by the Privacy Rule. The people who receive this information could use it in ways not discussed in this form and could disclose it to others. The sponsor will use and disclose your information only for research or regulatory purposes or to prepare research publications. In addition to using it for this study, the sponsor may reanalyze the study data at a later date or combine your information with information from other studies for research purposes not directly related to this study. The goal of any such research would be to learn more about drugs or diseases or to help design better studies in the future. When using your information in these ways, the sponsor may share it with regulatory authorities, other researchers, or companies it hires to provide research-related services.

WHAT HAPPENS IF I LEAVE THE STUDY EARLY?

If you stop participating in the study early for any reason, the study team will tell the sponsor why. If the study team asks you to come to any more study visits and you agree, the study team will send the sponsor information from those visits as well. All information collected about you may continue to be used and disclosed.

WILL MY AUTHORIZATION EVER EXPIRE?

This Authorization does not have an expiration date. The study team may need to correct or provide missing information about you even after your study participation is over and a review of your medical records may also take place after the study is over.

MAY I TAKE BACK MY AUTHORIZATION?

You have the right to take back (revoke) your Authorization at any time by writing to the person in charge of this research study whose information is listed on the front of this form. If you revoke your Authorization, the study team will not collect any new health information about you. However, they can continue to use and disclose any already-collected information if that is necessary for the reliability of the study. The sponsor can also still keep and use any information that it has already received. If you revoke your Authorization, you can no longer continue to participate in the study.

MAY I LOOK AT MY STUDY INFORMATION?

You have a right to see and make copies of your medical records. However, to ensure the reliability of the study, you will need to wait to see your study-specific records until after the study is completed.

WHO DO YOU CALL IF YOU HAVE QUESTIONS OR PROBLEMS?

If you have questions, concerns, complaints and/or suggestions about this research study or to report a research-related injury, please contact the researcher, Dr. Judith Feinberg at (513) 584-6977.

Please call the University of Cincinnati Institutional Review Board at 513-558-5259 (Monday – Friday 8 am to 5 pm) if you:

- Think the research has hurt you.
- Have general questions about giving consent or your rights as a research participant in this research study.
- Have questions, concerns, complaints and/or suggestions about the research.
- Cannot reach the research team or you want to talk to someone else.

To report complaints or concerns to an independent agency in an anonymous and confidential manner, please call the Research Compliance Hotline at 1-800-889-1547.

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Study Title: Southern Ohio Prevents Hepatitis C (StOPHEP)

UC IRB Study #:

Sponsor Name: U.S. Centers for Disease Control and Prevention

Investigator Information:

Dr. Judith Feinberg	(513) 584-6977
Principal Investigator Name	Telephone Number 24 hr Emergency Contact

I have read or someone has read to me, this Informed Consent Document that describes the purpose and nature of this research. I have had time to review this information and have been encouraged to ask questions. If I do not participate or if I discontinue my participation, I will not lose any benefits or any legal rights. My participation in this research is completely voluntary. I have received (or will receive) a copy of this signed and dated form for my records and future reference. I have been given the information about the use and disclosure of my health information for this research study.

I give my consent to participate.
I authorize the release of information concerning treatment relating to…

- HIV testing
- AIDS or AIDS related condition,
- psychiatric condition(s)
- alcoholism
- drug abuse

…to the parties listed in the authorization section of this consent for the purposes described above.

Participant	Date

PERSON OBTAINING CONSENT
I have read this form to the participant and/or the participant has read this form. An explanation of the research was given and questions from the participant were solicited and answered to the participant's satisfaction. In my judgment, the participant has demonstrated comprehension of the information.

Signature and Title of Person Obtaining Consent and Identification of Role in the Study	Date