OREGON HEALTH & SCIENCE UNIVERSITY

Information Sheet and Authorization
Usual Care

IRB# 26983

TITLE: Dried Blood Spot Testing in Peer-assisted Telemedicine for Hepatitis C Treatment (DBS TaT)

PRINCIPAL INVESTIGATOR: Hunter Spencer, DO (503) 681-4233

WHO IS PAYING FOR THE STUDY?: Collins Medical Trust, NIH National Center for Advancing Translational sciences

WHY IS THIS STUDY BEING DONE?:
You have been invited to be in this research study because you have tested positive for hepatitis C (HCV) and are being treated through the Peer Assisted Telemedicine for Hepatitis C (PATHS) program. The purpose of this study is to compare starting HCV treatment using peer-assisted telemedicine and a blood draw (usual care) versus using a new workflow, called Dried Blood Spot Test and Treat (DBS TaT). DBS TaT uses dried blood spot tests to confirm HCV infection, a questionnaire to determine risk level of liver fibrosis (liver scaring that is sometimes caused by hepatitis C), and those at low risk can start HCV treatment before completing the usual tests for liver fibrosis. We hope to learn about ways to streamline HCV testing and treatment.

For this study, clinic sites have been randomized (like flipping a coin) to either continue using the usual care procedures or use the new DBS TaT procedures to test for and treat HCV. This clinic has been randomized to offer the usual care procedures.

We are also asking you to provide information for a data bank, also called a repository. These data will be stored indefinitely and may be used and shared in the future for research.

WHAT TESTS AND PROCEDURES ARE INVOLVED IN THIS STUDY?:
This study will collect information about medical conditions and recreational drug use. If you agree to participate in this study, you will be asked to complete two short questionnaires at the time of your telemedicine visit before meeting with the PATHS provider.

The Decompensated Cirrhosis in Hepatitis C Evaluation Questionnaire (DCHEQ) is a short questionnaire designed to help determine your risk of liver fibrosis. This should take about 5 minutes to complete.

The Baseline Survey assesses substance use and risk factors for conditions that can also occur with substance use, like human immunodeficiency virus (HIV). You will be asked questions about education, sexual orientation, substance use, sexual activity, and HIV prevention. This survey should take about 10 minutes to complete.

Transient Elastography: You will be asked to complete transient elastography (ultrasound scan of the liver) either before or after starting HCV treatment. This is a non-invasive imaging test that measures how much scarring has occurred in the liver (liver fibrosis). To do this test you would schedule an appointment. This is a standard imaging test that is not painful and does not have long term side effects.

We will also ask you questions to help fill out an Enrollment Form . This will also help us to find a way to contact you with your results.

Participation in the study will be ongoing until HCV test results show it has been cured. These results will be obtained through your medical record. HCV treatment lasts 8-12 weeks. It is recommended that you complete the test 12 weeks after the last dose of medication. Participants who do not complete a test of cure by 24 weeks after treatment completion will be considered lost to follow up. Overall, participation in this study should last up to 36 weeks.

If you have any questions, concerns, or complaints regarding this study now or in the future, or you think you may have been injured or harmed by the study, contact Hunter Spencer at 503-681-4233.

In the future, your information may be given to researchers for other research studies. The information will be labeled as described in the **WHO WILL SEE MY PERSONAL INFORMATION?** section.

WHAT RISKS CAN I EXPECT FROM TAKING PART IN THIS STUDY?:
Confidentiality: Although we have made every effort to protect your identity, there is a minimal risk of loss of confidentiality.

DCHEQ: There is a risk that you may be inappropriately scored by the DCHEQ as "low risk" for fibrosis and could be started on HCV treatment prior to identifying your true hepatic fibrosis status. This could increase the risk that you take an inappropriate hepatitis C medication that in rare instances could cause harmful side effects.

Baseline Survey: The survey may be offensive because it addresses sensitive subjects such as sexual practices and substance use. You may skip any questions you do not wish to answer.

Transient Elastography (TEG): There is a risk of harm related to cost or time by being referred for transient elastography, which is not routinely required in PATHS clinical care. This is a non-invasive imaging technique (scan) that can cause mild discomfort. TEG is covered by Oregon Medicaid insurance. If you have other insurance, you can confirm cost with your insurance company before completing the scan.

WHAT ARE THE BENEFITS OF TAKING PART IN THIS STUDY?:
You may or may not benefit from being in this study. However, by serving as a subject, you may help us learn how to benefit patients in the future.

You may benefit from completing transient elastography, a more precise test of liver fibrosis than what is usually performed in PATHS. You may also benefit by potentially starting HCV treatment without having to get a blood draw.

WHAT ARE THE ALTERNATIVES TO TAKING PART IN THIS STUDY?:
You may choose not to be in this study. If you choose not to be in the study, you will still be offered HCV treatment.

WILL I RECEIVE RESULTS FROM THIS STUDY?
We will give you the results of your DCHEQ. If you are at "high risk" of liver fibrosis, PATHS providers will assess hepatic fibrosis and make treatment recommendations using their clinical judgement.

You can receive the results of all screenings and tests associated with usual clinical care for HCV treatment. This information can be provided to you through PATHS peers or providers.

WHO WILL SEE MY PERSONAL INFORMATION?
In this study we will take steps to keep your personal information confidential, but we cannot guarantee total

privacy. However, we will do our best to keep your information confidential by keeping it coded and on an encrypted computer. To help us protect your privacy, we have obtained a Certificate of Confidentiality to protect your privacy even from people who try to get your information using a court order. One exception is if you agree that we can give out research information with your name on it. Another exception is information about child or elder abuse or neglect and harm to yourself or others or communicable disease reporting. Note that this doesn't prevent you from releasing the information yourself.

We may request your social security number in order to process any payments for participation.

As part of the study, OHSU has engaged with a vendor, Visa Vanilla Gift Card, to process and send you your compensation (discussed below). The study team will send your personal information (like name, address, email address, etc.) to coordinate payments to you. You can choose to receive email communications from Vanilla Gift Card to the personal email address you provide. These messages may contain information that you wish to keep confidential. Most modern email systems send and receive emails securely. However, your personal email provider may not be able to accept secure emails. There is a risk that those unsecure emails could be intercepted or viewed by other people and would no longer be confidential. There is also a risk that emails could be misdirected or viewed by other people who have access to your email account.

If, at any point, you no longer wish to receive emails from Vanilla Gift Card, tell the study team by sending an email to pathsprogram@ohsu.edu or 541-404-4408 and they will stop sending you emails. When your information is released to Vanilla Gift Card, it may no longer be protected under federal or Oregon law.

We may have to release this information to others for example, if the study is audited. However, we would try to do so without information that could identify you. This release could be to the Institutional Review Board (ethics review committee) at OHSU, the funder of the study, the FDA or Office of Human Research Protection (agencies that oversee research).

If your information goes outside of OHSU, it might not be protected under federal law from being used or further shared. We would like your permission to keep your data indefinitely. If you decide you don't want us to use your name and information for this or future research, you can request this by contacting us at:

Hunter Spencer, DO
Division of General Internal Medicine
Oregon Health & Sciences University
3181 SW Sam Jackson Park Rd
Portland OR 97239
spencerh@ohsu.edu

Your request will be effective as of the date we receive it. However, health information collected before your request is received may continue to be used and disclosed to the extent that we have already acted based on your authorization.

You do not have to allow the use and disclosure of your health information in the study, but if you do not, you cannot be in the study. If you choose not to participate, or if you decide to stop at any time, that will not affect your ability to receive health care at OHSU or insurance coverage.

WILL ANY OF MY INFORMATION OR SAMPLES FROM THIS STUDY BE USED FOR ANY COMMERCIAL PROFIT?

Information about you or obtained from you in this research may be used for commercial purposes, such as making a discovery that could, in the future, be patented or licensed to a company, which could result in a

possible financial benefit to that company, OHSU, and its researchers. There are no plans to pay you if this happens. You will not have any property rights or ownership or financial interest in or arising from products or data that may result from your participation in this study. Further, you will have no responsibility or liability for any use that may be made of your samples or information.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

You or your insurance company will be responsible for all costs related to participation in this study. You will be responsible for any costs your insurance does not cover. If you have any questions about these costs, or what out-of-pocket expenses you may be responsible for, contact your insurance company

You will receive $50 for completing the transient elastography if the test is scheduled within 50 miles from the site where you enrolled. If the distance is over 50 miles, the incentive will be $75. You will need a physical address or an electronic mailing address (Email) to receive compensation. We may be able to help you with setting up the email.

You will receive payment via a visa gift card.

WHERE CAN I GET MORE INFORMATION?

This research is being overseen by an Institutional Review Board ("IRB"). You may talk to the IRB at (503) 494-7887 or irb@ohsu.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get more information or provide input about this research.

You may also submit a report to the OHSU Integrity Hotline online at https://secure.ethicspoint.com/domain/media/en/gui/18915/index.html or by calling toll-free (877) 733-8313 (anonymous and available 24 hours a day, 7 days a week).

A description of this clinical trial will be available on https://www.clinicaltrials.gov as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

When visiting this website, use the search terms "Hepatitis C", "Dried Blood Spot" and "NCT06409169" to locate information on this trial.

DO I HAVE TO TAKE PART IN THIS STUDY?

You do not have to join this or any research study. If you do join, and later change your mind, you may quit at any time. If you refuse to join or withdraw early from the study, there will be no penalty or loss of any benefits to which you are otherwise entitled.

HOW DO I TELL YOU IF I WANT TO TAKE PART IN THIS STUDY?

Please indicate whether you provide your consent to participate in this study verbally by telling me "Yes, I would like to participate in the study" or "No, I would not like to participate in the study."