Clinical Study Informed Consent Form

A COMMUNICATION -BASED STUDY FOCUSED ON ASSESSING AND IMPROVING HEPATITIS C SCREENING RATES, AS WELL AS TREATMENT RATES IN ARIZONA AS A STEP TOWARDS DISEASE ERADICATION

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LIST OF ABBREVIATIONS AND DEFINITIONS OF TERMS

Abbreviation:	Definition:
AE	Adverse Event
ADHS	Arizona Department of Health Services
CDC	Center for Disease Control
ELISA	Enzyme-linked Immunosorbent Assay
HCV	Hepatitis C Virus
IEC	Independent Ethics Committee
IRB	Institutional Review Board
PCR	Polymerase Chain Reaction
PHI	Protected Health Information
Hep C Antibody Screening	A test used to screen for hepatitis C by identifying antibodies the body makes in response to HCV infection.
Hep C RNA Test	A more accurate test used for diagnosing hepatitis C by measuring the number of HCV genetic material (viral RNA).

The Informed Consent Process

You are being asked to participate in a clinical research study with the Liver Institute PLLC. The Liver Institute will oversee and is responsible for this study. Your participation in this study is entirely voluntary and will not affect your current medical care.

You may be eligible to participate in this study if you meet certain requirements. Before you decide to participate, you will need to understand the purpose of the study, the possible risks and benefits, and what would be expected of you. This process is called Informed Consent.

This document is an Informed Consent Form. Please read this entire document carefully. Take time to ask the study doctor or study staff as many questions about the study as you would like. If there are any words or information in this document that you do not understand, please ask the study doctor, or study staff, to explain them to you.

If you agree to participate in this study, you must sign and date this consent form before any study-related tests or treatments are performed. A copy of the signed, dated document will be given to you.

To protect your safety, rights, wellbeing, and dignity, all information from this study is reviewed by an independent group of people called an institutional review board (IRB.)

This study is funded by the Liver Institute PLLC.

What does this Informed Consent Form describe?

- The purpose and procedures of the study
- Possible risks and benefits you may experience
- How your personal and health information will be used and disclosed in this study, and requests your permission for that use and disclosure
- Your privacy rights in connection with the personal health information collected from or shared by you in connection with the study
- What compensation and/or medical treatment is available to you if injury occurs
- Who you can contact if you have questions about the study
- Your rights as a research participant

Summary of Key Information

Study Purpose

You are being asked to participate in a research study because you qualify for enrollment based on the inclusion/exclusion criteria for the research study. The purpose of this study is to eradicate the prevalence of Hepatitis C in Arizona through improving awareness, increasing population screening rates, and providing linkage to care.

The targeted study population consists of the entire Arizona population 15+ years of age. This is a total of 5,606,808 people. The expected response rate is about 2% (112,136 Arizonans.)

The approximate duration per subject is between 3-6 weeks. The entire length of the study is approximately 5 years.

Study Procedures

- Screening Promotion

A time limited screening test promotion code, specific to educational outreach methods, will be obtained from Liver Institute PLLC and advertised in both direct and indirect communication methods. Interested individuals would be required to present a specific promotional code and sign this Informed Consent Form.

- Screening Locations

Screening will take place in all branches of Sonora Quest Laboratories over the state of Arizona. Patients will have the opportunity to present at any of the locations and get free screening regardless of their insurance coverage or whether they are considered at risk or not.

- Informed Consents

The study, expectations and rights will be explained to patients in this form. Informed consents will be obtained electronically by the screening team to perform anti- HCV test, to share personal information and test result with Liver Institute study investigator team, and to agree to discuss treatment options if HCV test become positive. Consents will be sent to the Liver Institute PLLC where they will be stored in an encrypted electronic data capture system as per Western Institutional Review Board (WIRB) guidelines.

- Clinical Parameters

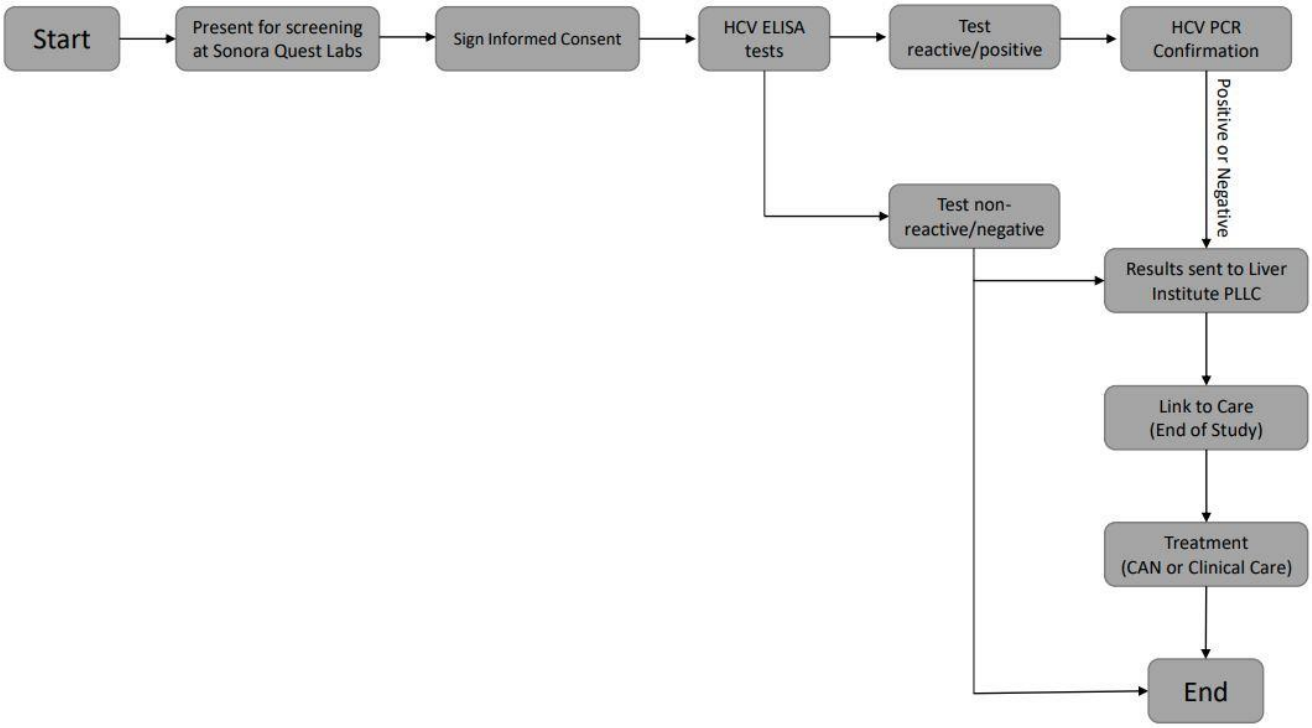
Demographics data and contact information will be recorded for each patient in Sonora Quest Laboratories data system as per their guidelines. Clinical and relevant history pertaining to hepatitis C including diabetes and existing conditions will be collected by the Liver Institute PLLC from HCV positive individuals.

- Screening

Screening will be conducted by members of the Sonora Quest Laboratories with ELISA IV antibody test with reflex to HCV PCR test to confirm the diagnosis. Patients will be contacted with their test results by a member of the research team, as well as by Sonora Quest.

- Treatment

In case of a positive test results, the project coordinator will communicate with the patients for treatment options. Project coordinator will identify HCV care provider for each HCV positive patient depending upon patient's insurance status. Project coordinator will help and facilitate assistance program applications to patients without insurance. The entire screening process is shown in the figure below.



Risks of Participation

The risks of participation are as follows:

- Blood Draw Risks:
    - Nerve damage
    - Uncontrolled bleeding
    - Bruising
    - Swelling
    - Infection

Blood draw risks very rarely result in serious complications. However, there is a very small possibility of complications arising. If this happens, contact your study coordinator immediately.

There may be risks related to the research that we do not know about yet. However, you will be informed of any additional risks to which you may be exposed, and any changes that are made to the study, as a result of any newly identified risks.

Benefits to Participation

The benefits of participation are as follows:

- Subjects will have access to free Hepatitis C testing.
- Subjects with a positive initial test will have the opportunity to undergo a second test to confirm the positive result.
- Subject with 2 positive tests will be connected to an HCV care provider for treatment depending on the subject's insurance status.
    - Subjects without insurance will be assisted by the Study Coordinator to get qualified for an assistance program that will pay for the treatment medication.
- Subjects will be made aware of a potentially asymptomatic condition and have access to treatment to prevent further liver damage (including the potential for developing liver cancer.)

- Subjects will be assisting with the eradication of Hep C in Arizona
- Subjects will be assisting with the World Health Organization's goal to eradicate Hep C by 2030.

Alternatives

There are no alternative treatments or procedures available. The only alternative is not to participate in this study.

Confidentiality

Anonymity of subjects participating in this study will be maintained. Every effort will be made to maintain the confidentiality of documents that identify the subjects by name (e.g., signed informed consent document and patient data).

The investigator and other study site personnel will keep confidential any information related to this study and all data and records generated while conducting the study, and will not use the information, data, or records for any purpose other than conducting the study. These restrictions do not apply to:

1. Information which becomes publicly available through no fault of the investigator or study site personnel
2. Information which it is necessary to disclose in confidence to an IRB/EC solely for the evaluation of the study

   or

3. Study results which may be published. If a written contract for the conduct of the study which includes confidentiality provisions inconsistent with this statement is executed, that contract's confidentiality provisions shall apply rather than this statement.
4. Protected health information will be shared with CAN Community Health

Essential documents, as described above, should be retained for at least 2 years after conclusion of the study. Institution and the investigator shall have the right, consistent with academic standards, to publish or present the results of the study, provided such publication or presentation does not disclose confidential information.

Eligibility Requirements

- Subjects must sign the consent to screen and take part in the study.
- Subjects must be at least 15 years of age.
- Patients may only be enrolled once.
- Patients who do not meet the inclusion criteria will be excluded.
- Patients with a current HCV diagnosis will be excluded.
- Patients who underwent a liver transplant will be excluded.

Incidental Findings

During this study, you will potentially have 1-2 blood draws. These blood draws are for research purposes only. The purpose of the blood draw is to look for blood markers related to hepatitis c. This is not a complete panel of blood components as would be drawn by your primary care physician however, there is a chance that the blood draw will show something in addition to what the research study is designed to find. We refer to any finding that is in addition to the purpose of the research study as an "unexpected finding." Because we are not in a position to determine what significance, if any, there is to an unexpected finding, if there is an unexpected finding, the finding will be shared with you along with a copy of the bloodwork to take to your primary care physician for further review. If you do not have a primary care physician, ask the research team for a list of current primary care providers.

Reproductive and Transmission Risks

If you are tested positive, you should not become pregnant before treatment and confirmation via a negative test after treatment. Hepatitis C can be transferred to an unborn child via the mother only. Hepatitis C cannot be transferred through breast milk. Sexual transmission of Hepatitis C can happen but is unlikely. Hepatitis C can be spread when the blood of an infected person gets into the blood of a person who is not infected. If you are female and get pregnant after a positive test but before treatment, you should notify the study doctor immediately. Pregnancy testing will not be included in the study.

Compensation

You will not be compensated for your participation in this research study. For subject who do not have medical insurance, the study coordinator will work with CAN community health to get government assistance to cover the Hepatitis C treatment costs only per 340B eligibility requirements. You will not receive reimbursement for any out-of-pocked expenses, such as transportation fees or parking.

There is not a cost to you for your participation in the blood draws for this study. If you test positive, the study coordinator will work with you to find a provider to order treatment. This treatment will be billed to your insurance, unless uninsured. You and your insurance will be responsible to cover the cost of the treatment medication. Your insurance will be billed for the costs of any standard medical care you receive to diagnose and/or treat any medical condition(s) outside of this study. You will also be responsible for any deductibles or co-payments that would normally be associated with these standard medical costs. There may be unexpected out-of-pocket costs, such as for transportation.

What happens if I want to stop participating in this study?

You are free to withdraw from this study at any time. If you decide to withdraw from this study, you should notify the research team immediately. The research team may also end your participation in this study if you do not follow instructions, miss scheduled visits, the study sponsor decides to stop the study, or your safety and welfare are at risk.

If you experience any of the side effects listed above, if your health worsens, or if you are injured during the research, you may need to be withdrawn from the study, even if you would like to continue. The research team will make this decision and let you know if it is not possible for you to continue. The decision may be made to protect your safety and welfare, or because the research plan does not allow people who develop certain conditions to continue to participate.

If you withdraw or are removed from the study, the researcher may ask you follow up questions, including but not limited to why you no longer wish to participate. If you elect to withdraw or are withdrawn from this research study, the data collected from your participation in this study must remain in the trial database in order for the study to be scientifically valid.

If you elect to withdraw or are withdrawn from this research study, you may choose to terminate the continued use or disclosure of your protected health information (PHI) for research purposes. The request to end the use or disclosure of your PHI should be made in writing.

If you elect to withdraw or are withdrawn from this research study, the researchers will discuss with you what they intend to do with your study data. Researchers may choose to analyze the study data already collected or they may choose to exclude your data from the analysis of study data and destroy it, as per your request.

You are free to withdraw your consent to use your identifiable private information and biospecimen for future research at any time however, there are some limitations. If you withdraw your consent, the researchers will not use your information or biospecimens in future research studies. However, any of your information or biospecimens already being used in a research study that began before your request to withdraw will continue to be used for that specific study. Also, if information and biospecimens have already been provided to another researcher, institution, or company, it may not be possible to limit their continued and new uses.

How will information about me and my participation be kept?

Identifiable information collected about you will be removed and replaced with a code. A list linking the code and your identifiable information will be kept separate from the research data. This list will be kept strictly confidential and accessed only by those authorized by the study doctor. Research data will be stored electronically on a secure computer and network in an encrypted file with password protection.

The research team, authorized Liver Institute or Sonora Quest personnel, the study sponsor, and regulatory entities such as (but not limited to) the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP), may have access to your study records to protect your safety and welfare. While the research team will make every effort to keep your personal information confidential, it is possible that an unauthorized person might see it. We cannot guarantee total privacy.

Researchers will use your results and information to conduct this study. Once the study is done using your results and information, we may share them with other researchers so they can use them for other studies in the future. We will not share your name or any other private identifiable information that would let the researchers know who you are. We will not ask you for additional permission to share this de-identified information.

If you agree to participate in this research study, a signed copy of this consent document and the privacy authorization form may be filed in your electronic medical record (EMR) and your study participation may be added to your EMR. This information will be used for your care and treatment and for healthcare operations, which may include billing and payment. Biospecimens (such as blood) collected for Hepatitis C testing will be discarded or destroyed once they have been used for the purposes described in this consent.

Investigator Financial Conflict of Interest

No one on the study team has a disclosable financial interest related to this research project.

Who do I contact with my questions about the study?

If you have any comments, concerns, or questions regarding the conduct of this research, please contact the research team listed at the top of this form. A 24-hour number is also listed on the top of this form to report any health concerns or unanticipated problems you may experience after normal hours or on weekends.

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number(s) listed above on the first page.

This research is being overseen by WCG IRB. An IRB is a group of people who perform independent review of research studies. You may talk to them at 855-818-2289 or researchquestions@wcgirb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject

What is an IRB?

An Institutional Review Board (IRB) is a committee made up of scientists and non-scientists. The IRB's role is to protect the rights and welfare of human subjects involved in research. The IRB also assures that the research complies with applicable regulations, laws, and institutional policies.

What are my privacy rights?

You have the right to access, through your study doctor, all the information collected about you in your medical record, and to ask for corrections, according to the rules of the study site. You have the right to request information on how the Personal Information reported to the Sponsor is being used and with whom the data have been shared.

Please note that your right to access certain information in your medical records may be suspended during your participation in the study. Therefore, if you would like immediate access to your records, you may not be able to continue participating in the study.

To participate in this study, the Sponsor must collect and use your Personal Information. Your decision to allow the collection and use of your health information is completely voluntary but if you do not allow it, you may not participate in the study. If you decide that you do not want to participate in the study any longer or change your mind about your Personal Information being used, you can voluntarily withdraw from the study at any time. You can do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to continue being in the research study. If you choose not to participate, or choose to stop participating, you will not be punished in any way or lose any right to access care, treatment, or services outside of the study. Your decision not to participate in the study or to withdraw later will have no penalty or loss of benefits to which you are otherwise entitled.

If you decide to discontinue being in the study, you should let the study doctor know before you stop. If you do not return to the study center, you may be contacted to determine whether there have been changes in your health.

If you withdraw your permission to use your Personal Information, the Personal Information collected prior to your withdrawal will still be processed along with other data collected as part of the study to preserve the integrity of the results and in accordance with regulatory requirements.

The information collected about you up to the point when you discontinue from the study, or information obtained after you discontinue in connection with a safety issue related to the study, will continue to be used, including laboratory results, clinic notes, and any other information collected. However, no new information will be collected unless you specifically consent to that or have a side effect related to the study. The information in this form reflects what is known about the study at the time it is signed. If any significant new information is discovered during the study that may affect whether you want to continue to take part in the study, you will be informed in a timely manner.

If you withdraw from the study but do not withdraw your Authorization, new health information may be collected until this study ends. If you withdraw from the study, you may also request that the Personal Information already collected from you in connection with the study be deleted. However, your right to deletion is limited due to regulatory requirements and to preserve scientific integrity, as your Personal Information must be managed in specific ways for the research to be reliable and accurate. Your access to this information may be delayed until the study is complete.

A description of this clinical trial will be available on http://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. [21 CFR 50.25(c)]

How do I agree to participate?

You should not sign and date this consent form until all your questions about this study have been answered by a member of the research team. You will be given a copy of this signed and dated consent form. **Participation in this study is voluntary, you are not being forced to sign this document or participate in this research study.** You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your future relationship with the Liver Institute or your quality of care at the Liver Institute.

If, during this study, significant new information becomes available that may relate to your willingness to continue to participate, this information will be provided to you by the research team listed at the top of the form.

Your signature below indicates you have read the information in this consent form and have had a chance to ask any questions you have about this study.

I agree to participate in the study.

_____	_____
Subject Signature	**Date**
_____	
Printed Name of Subject	
_____	_____
Legally Authorized Representative/Guardian Signature	***Date***
_____	_____
Printed Name of Legally Authorized Representative/Guardian	***Relationship***
_____	_____
Signature of Person Obtaining Informed Consent	**Date**
_____	
Printed Name of Person Obtaining Informed Consent	