

## **Program Element #24: Multnomah County Hepatitis C Surveillance (MCHS)**

- 1. Purpose of MCHS.** Funds provided under the Agreement for this Program Element may only be used, in accordance with and subject to the requirements and limitations set forth below, to establish and conduct a population-based surveillance of persons in Multnomah County diagnosed with the hepatitis C virus (“HCV”), as reported to LPHA by medical laboratories in Multnomah County, to:
  - a. Describe the demographic and socioeconomic characteristics of persons with HCV infection in Multnomah County;
  - b. Estimate the burden of the disease among persons newly-identified with HCV;
  - c. Assess the need for medical and personal preventive services (e.g., health insurance status, access to primary and specialty care, history of vaccination against hepatitis A and B virus, current alcohol/drug use) in the subset of patients aged 18-30 years;
  
- 2. Definitions Specific to MCHS:**

**Hepatitis C Registry:** a database maintained by LPHA containing data on individuals with HCV, as reported to LPHA by medical laboratories in Multnomah County.
  
- 3. Procedural and Operational Requirements.** LPHA’s MCHS must be conducted in accordance with the following procedural and operational requirements:
  - a. LPHA must assign adequate staff to conduct the study. The assigned staff must include the following:
    - i. Research and Evaluation Analyst 1 (1.00 FTE) who must be assigned to conduct interviews of individuals diagnosed with HCV,
    - ii. Data Manager (0.35 FTE), and
    - iii. Program Manager (0.05 FTE) who must supervise the MCHS activities.
  - b. LPHA must establish and maintain a general surveillance system for individuals in Multnomah County newly-identified with HCV, by:
    - i. Maintaining the Hepatitis C Registry.
    - ii. Confirming the diagnosis of HCV of individuals reported to LPHA by medical laboratories in Multnomah County.
    - iii. Attempting to obtain minimal demographic and clinical data from each patient’s health care provider, using the form attached (Appendix A, Attachment 2)
  - c. LPHA must implement a more detailed surveillance system for a subset of the individuals aged 18-30 years in Multnomah County newly identified with HCV, by:

- i. Identifying individuals aged 18-30 years reported to the HCV Registry each month with a confirmed HCV diagnosis and recruiting those individual for a more thorough review of their socioeconomic characteristics, medical pathologies, risk factors for HCV and the need for medical and preventive services The individuals must provide informed consent, in accordance with the form attached hereto as Appendix A, Attachment 6 and incorporated herein by this reference, to the more thorough review.
- ii. Interviewing each individual who consented to the more thorough review to gather additional information. LPHA must use the form attached hereto as Appendix A, Attachment 1 and incorporated herein by this reference, to interview the individual.

4. **Reporting Obligations and Periodic Reporting Requirements.** In addition to the reporting obligations set forth in Section 8 of Exhibit E of this Agreement, LPHA shall provide written semi-annual progress updates describing participant recruiting efforts and characteristics of participating vs. non-participating individuals with confirmed HCV diagnoses and containing such additional information as may be required by the Centers for Disease Control and Prevention, the federal entity funding MCHS. LPHA shall submit the progress updates in accordance with a format and reporting schedule determined by Department in consultation with LPHA.

**Appendix A**  
**Multnomah County, Oregon Hepatitis C Virus Registry Study (MCHRS)**

**1. Project Overview**

**a. Protocol Summary.** We plan to interview and review medical charts of newly-identified persons aged 18-30 years testing positive for hepatitis C virus (HCV) reported by laboratories to the Multnomah County Health Department (MCHD). The interview will collect data on demographic characteristics; risk factors for infection; duration of infection; need for prevention and medical services, including health insurance status, access to appropriate care, and treatment for hepatitis C. We anticipate contacting enrolled patients in the future, as part of a longitudinal study and will submit a protocol for these follow-up activities should we decide to pursue them.

**b. Investigators.**

*Division of Viral Hepatitis, NCHHSTP (proposed), CDC*

- Stephanie Bialek, M.D., M.P.H.
- Beth Bell, M.D., M.P.H.

These CDC investigators provided guidance in developing the protocol. They will analyze and present data collected from this study.

*Oregon Public Health Division*

- Ann Thomas, M.D., M.P.H.

Ann Thomas will serve as consultant. She developed the study protocol and will be involved in data analysis and presentation.

Grace Van Ness, M.P.H.

Grace Van Ness will serve as local project coordinator, maintain the hepatitis C registry, track enrollment and conduct other data analysis projects, and serve as a secondary patient interviewer.

*Multnomah County Health Department*

- Diata Rhodes, M.A.

Diata Rhodes will obtain physician authorization to contact patients, contact patients, and perform patient interviews

*Oregon Health Sciences University*

- Atif Zaman, M.D., M.P.H.

Atif Zaman will serve as the local principal investigator. He participated in study protocol design, and will supervise local study staff and review clinical data to determine if study participants have chronic liver disease.

All investigators were involved in study design and the development of data collection instruments. Multnomah County Health Department investigators will recruit study participants, contact physicians, consent and interview study participants. Data entry will be performed at the Multnomah County Health Department and CDC. Multnomah County Health Department, CDC and Oregon Public Health Division (OPHD) investigators will be responsible for analyzing data, disseminating study results and writing manuscripts.

## 2. Introduction

- a. **Surveillance Aim and Objectives.** Our overall aim is to establish population-based surveillance for persons aged 18-30 years newly-identified with HCV infection in Multnomah County in order to develop individual and population-based prevention strategies. Our specific objectives are to:
- i. Describe the demographic and socioeconomic characteristics of persons aged 18-30 with HCV infection;
  - ii. Estimate the burden of disease among persons newly-identified with HCV infection;
  - iii. Estimate duration of infection;
  - iv. Assess stage of illness and the need for medical and personal preventive services (e.g., health insurance status, access to primary and specialty care, history of vaccination against hepatitis A and B virus, current alcohol/drug use). We will refer to community service agencies as appropriate;
  - v. Establish a population-based cohort of persons with HCV infection to follow longitudinally to evaluate the natural history of disease.
- b. **Background**

Hepatitis C is the most common blood-borne infection in the United States. It is estimated that 3.9 million people (1.8% of the population of the U.S.) have been infected with HCV, and of these individuals, 2.7 million remain chronically infected. Of those chronically infected, 10%-20% develop cirrhosis, and 1%-5% will die from hepatocellular carcinoma or complications of chronic liver disease. Risk factors for more rapid progression to cirrhosis include male sex, age > 40 years at time of infection, co-infection with human immunodeficiency virus (HIV) or hepatitis B virus (HBV), obesity and alcohol use. Hepatitis C virus infection has become the most frequent indication in the U.S. for a liver transplant, accounting for 37% of liver transplants in 2000. In 1997, the direct and indirect costs of HCV infection in the US were estimated at \$5.46 billion (comparable to the \$5.8 billion spent on asthma in 1994).

According to the Centers for Disease Control and Prevention (CDC), risk factors for HCV infection include contact with blood or body fluids from a person infected with HCV. This exposure can occur from injecting drugs, blood transfusions or solid organ transplants before July 1992, receipt of clotting factor(s) made before 1987, and long-term kidney dialysis. In the period 1995-2000, 68% of newly-acquired cases in the US occurred among injection drug users, 18% were sexually-acquired, and 4% occurred in occupational settings.

In 2000, a collaborative study between the Emerging Infections Program (EIP) of OHS and the Hepatology Research Clinic of the Oregon Health and Sciences University (OHSU) was funded by the CDC to conduct active surveillance in Multnomah County for persons newly-diagnosed with chronic liver disease (CLD). In the period 2000-2001, we searched through records of patients seen in gastroenterologist's offices and identified 752 persons with CLD, of whom 458 (61%) had hepatitis C. However, we also conducted several validation studies (using Medicaid data, death certificates, and a pilot study in OHSU outpatient clinics) that demonstrated that surveillance in gastroenterology offices only

detected a fraction of persons with CLD. Particularly for persons with hepatitis C, surveillance in gastroenterologists' offices is likely to miss persons who are un- or underinsured. In order to more fully describe the epidemiology and estimate the burden of disease of persons with HCV infection in Multnomah County, we need to develop a surveillance system that will capture a more representative group of persons with HCV infection.

In May 2000, under its authority to conduct "Special Epidemiologic Studies," the MCHD asked laboratories in the county to voluntarily report to them all persons who tested positive for HCV. Since 2001, the Multnomah County HCV Registry has received an average of 2,431 reports each year, with an average monthly total of 191 in 2003. On June 30, 2005, Oregon Administrative Rules (OARs) were revised to make all positive test results for HCV reportable by licensed clinical laboratories in the state. In collaboration with CDC, MCHD, and OHS, we propose to develop a population-based surveillance system for HCV infection in Multnomah County utilizing this registry.

### 3. Procedures and Methods

- a. **Case Definition.** Persons are eligible for enrollment into the MCHRS if the following inclusion criteria are met:

Multnomah County residents aged 18-30 years of age; and reported to the Multnomah County Health Department with any of the following HCV diagnostic tests:

- i. High HCV enzyme immunoassay (EIA) signal/cutoff ratio  $\geq 3.8$ ; or
  - ii. positive qualitative HCV RNA; or
  - iii. positive quantitative HCV RNA; or
  - iv. positive recombinant immunoblot assay (RIBA); or
  - v. an HCV genotype has been identified.
- b. **Justification of Exclusion of any Sub-Segment of Population.** We do not plan to enroll minors since they comprise only a small fraction of persons reported to the registry (22 or <1% in 2005). Similarly, we do not plan to enroll persons who are currently incarcerated at the time of study enrollment, since they comprise only 5%-6% of patients reported to the HCV registry.
- c. **Case Finding.** In order to allow time for patients to receive their HCV test results before we attempt to contact them for the study, we will wait until 2 months after test results are reported before selecting patients to recruit for the study. Each month we will select patients reported to the HCV registry 2 months ago and review their test results to determine if they meet our inclusion criteria.

Because hepatitis C is reportable in Multnomah County, we will fax an initial provider form for all persons testing positive for hepatitis C (Attachment 2). The fax form collects demographic, testing and clinical information as part of routine communicable disease surveillance.

We will attempt to enroll all newly-diagnosed patients meeting the case definition (~20-25 patients each month). Staff will obtain copies of original laboratory results to verify results and minimize errors.

- d. Patient Recruitment and Enrollment.** Once eligible patients are identified, project staff at MCHD will fax an information letter (Attachment 3) about the study to the provider listed on the laboratory report. Providers will be requested to fax a form back stating that they give their consent for us to contact the patient and verifying that the patient has already received the results of their HCV test(s). If no response is received in one week, project staff will telephone the provider to ask permission to contact the patient. In rare instances, it may be necessary to contact the patient's health care provider to clarify their response (i.e. provider may state that patient is not suitable for the study for a seemingly inappropriate reason). In these instances, the principal investigator will contact the patient's health care provider, document the conversation, and communicate the outcome with study staff. After a period of one month, if the patient's health provider does not respond to the previously faxed information letter or the follow up telephone call from project staff, study staff will contact the patient directly. If a health care provider refuses to allow a patient to be recruited for the study but does not submit an assent form until more than a month has elapsed, our response will depend on whether the patient has already been contacted by study staff. If the patient has already been contacted and has consented to participate, study staff will enroll the patient provided that the patient can truly provide informed consent (i.e. the patient has no physical or psychiatric co morbidities that may interfere with the informed consent process). If the patient has not yet been contacted by study staff, the principal investigator may contact the clinician to discuss whether the refusal was appropriate.

If a patient has been tested through the MCHD HCV testing program (which is conducted at STD clinics; HIV counseling and testing sites; and through outreach to correctional facilities, drug treatment centers and needle exchange sites), we will ascertain from MCHD Hepatitis C outreach staff whether the patient has returned for post-test counseling. If not, an attempt will be made by MCHD Hepatitis C outreach staff to contact the patient to notify them of their results, using the Hepatitis C outreach program's usual procedures to contact patients (their normal procedure is to mail a letter 2 weeks after the test results have been reported to the outreach program). We will not attempt to enroll patients who have been tested through the MCHD HCV outreach program unless we can verify that they have received their test results and post-test counseling.

Lastly, patients who were tested in certain types of facilities (hospital emergency rooms, occupational health settings, and blood and plasma donation centers) are unlikely to have an ongoing relationship with a provider who can assure that they are aware of their results. In accordance with MCHD's usual practice for investigating other notifiable diseases occurring in patients originally tested in one of these settings (hospital emergency rooms, occupational health settings, and blood and plasma donation centers), we will not attempt to contact the patients' providers before attempting to contact the patient. If in our initial contact we find that the patient is unaware of their positive HCV test result and does not have a health care provider who can counsel the patient about the meaning of their test results, we will offer to give the individual their test results at that time. We will also offer post-test counseling by telephone and refer the individual to local agencies that support persons with HCV. We will not attempt to enroll these patients into the study at the time

of this initial encounter. However, we will re-contact the person approximately two weeks after to ascertain whether the patient is interested in enrolling into the study.

Once we have obtained authorization from the patient's health care provider, a letter stating that the patient may be eligible for a study on hepatitis based on some recent tests that they have undergone will be mailed to each eligible subject (Attachment 4A), and the patient will be asked to contact MCHD by calling the health department or returning the enclosed response-card in the self-addressed response envelope provided (Attachment 4C) if they are interested in participating.

If the eligible subject does not reply within two weeks, MCHD staff will also attempt to contact the patient by telephone (Attachment 5B). We will also initially start attempting to contact patients by telephone if no mailing address is available (Attachment 5A). A total of 10 attempts will be made, starting with 5 attempts during normal working hours 3 attempts during weekday evenings, and 2 attempts on weekends. An attempt to contact potential participants is defined as any of the following: dialing a number and getting no answer, dialing a number and getting a busy signal, dialing a number and getting an answering machine, or dialing a number but the potential participant is not available to come to the phone. Interviewers will not leave any information about why they are calling if they reach any person other than the potential study participant. If they reach an answering machine, they will leave a brief message for the intended patient saying that they have been selected to be in a study and should call back for more information (Attachment 5A). The voicemail message will not mention hepatitis or the Multnomah County Health Department in order to maintain confidentiality about the patient's diagnosis. If we are not able to contact the patient, we will mail a self-administered version of the questionnaire (Attachment 1B), along with a letter (Attachment 4B) describing the study and a self-addressed stamped envelope. We would request that if they are interested in participating in the study, they complete the questionnaire and return it to us in a self-addressed return envelope. Patients who return the questionnaire will receive \$25 for their time and effort to complete the questionnaire.

When contact is made with an eligible subject by telephone, study staff will verify that subject has already received their test results. If not, MCHD study staff will recommend that the patient returns to their usual provider to find out their test results and make arrangements to re-contact the patient about the study at a later date. For patients who are aware of their results and who are interested in hearing more about the study, study staff will briefly describe the study and ask if they are interested in enrolling in the study.

All patients who are willing to travel to the MCHD for the interview, whether at home, at their work place or other mutually agreed upon site, will receive \$50 for their time and either the inconvenience of having an interviewer visit their home or work place, or travel expenses. Lastly, we will offer the option of a telephone interview to potential subjects. Subjects who agree to a telephone interview will receive \$25 for their time. Study staff will obtain patient consent over the phone (Attachment 6), and either conduct the initial patient interview (Attachment 1 at that time or schedule a convenient time to conduct the interview later. For persons who prefer to complete the interview by phone, we will obtain verbal consent. In addition, a written copy of the consent form will be mailed to the patient to sign and mail back to study staff at MCHD. We are requesting a waiver documentation of written consent. We will attempt to obtain written consent from all participants but will use

data from those participants that give verbal consent for a phone interview but then later fail to return a signed copy of the consent form.

- e. **Study Instruments.** A standardized questionnaire will be used to interview all enrolled patients (Attachment 1). The interview will collect demographic characteristics; medical history, such as other medical conditions, history of hepatitis C-related hospitalizations, and complications of hepatitis C and chronic liver disease; risk factors such as injection drug use, history of transfusion or dialysis, occupational exposure, household contact with a person with hepatitis C, and high-risk sexual practices; duration of infection, based on date of identified risks (e.g., onset of injection drug use); need for prevention services, such as receipt of hepatitis A and B vaccines and alcohol, drug, alcohol or mental health treatment; and need for medical services, including health insurance status, access to appropriate care, and whether the diagnosis has been confirmed. In addition, patients will be given the Beck Depression Inventory and the Primary Care Mood Disorders Questionnaire to complete as part of their appointment.
  
- f. **Data Management.** Participants will be assigned a study identification number at MCHD. Data collection forms will be stored using only the study ID and not names. Study documents will be kept in locked files and password protected databases to which only study personnel will have access. The study ID linking patient names with study identification numbers will be maintained in a separate, password-protected database. Personal identifiers will be removed from any records, documents, reports, forms, or databases sent to CDC. Data collection forms will be kept at Multnomah County Health Department for data entry. Data entry will be performed using Microsoft Access. All communications or transfer of information regarding patients between the MCHD and CDC will be done using the study ID—we will only transmit electronic datasets to CDC with personal identifiers deleted.

In some instances, interviewers may conduct interviews from home since some participants may only be available after business hours, during evenings and weekends. In these cases, interviewers would need to transport completed interview forms back to the office. They would do this by carrying the data in a locked brief case in the trunk of their car. They would drive directly from home to work so that the car would not be unattended at any time that the data was in it. When conducting interviews at home, interviewers will work alone without any other household members present or within earshot and with the door to the room closed. After completing interviews, the staff member will transfer study files with personal identifiers to a locked file cabinet in their home for storage until they return to the office on the next business day.

- g. **Data Analysis Plan.** Age-, race-, and sex-specific rates of newly-identified cases of HCV infection and associated HCV complications will be calculated using population denominators from the most recent census data available (2001 or 2002) for individuals >18 years of age. Epidemiologic characteristics of newly-identified cases of HCV infection will be summarized using standard descriptive statistics. Data analysis will be performed using SAS software. Multnomah County Health Department, Oregon Health Services and CDC will have access to the final dataset. Annual summaries of the data are planned.

- h. Limitations of the Study.** There are three potential sources of bias for this proposed surveillance system. First, not all patients with HCV infection receive testing. The majority (70%-80%) of patients may not have any symptoms at the time they are infected, and the sequelae of chronic liver disease may not appear until 10-20 years later. The single biggest risk factor for acquiring HCV infection is injection drug use (IDU), and many persons actively engaged in IDU are not likely to seek medical care.

Secondly, not every patient with a positive HCV test reported to the MCHD HCV registry has sufficient data reported to the registry for the patient to meet our case definition, and this lack of data could be a source of bias if certain groups of patients (e.g. uninsured or under-insured patients, active injection drug users) were less likely to have been appropriately evaluated for HCV infection. We have sought to minimize this as a source of bias by working with local laboratories to improve their reporting of the signal-cutoff ratio on the enzyme immunoassay (EIA), which is the least expensive and preferred initial screening test for HCV infection. For the period September 1, 2003 through January 31, 2004, we have found insufficient data for only 9% of patients reported to the registry.

Lastly, we may have difficulty locating every individual reported to the registry, which could bias our results if missing contact information is not a randomly distributed characteristic. For the period September 1, 2003 through January 31, we found that 27% of patients reported to the registry lacked both address and phone number on the laboratory report. We plan to minimize this potential source of bias by contacting providers of patients whose addresses or phone numbers are missing from the initial laboratory report. Additionally, for patients who do not have a clinician because they were tested in conjunction with HIV testing or identified by MCHD outreach workers, we will work with the MCHD staff that conducted the hepatitis C pre-test counseling to find these patients.

- i. Protection of Human Research Participants.** Informed consent will be obtained by study personnel who are employees of either the OHS Oregon Public Health Division or the MCHD. When conducting interviews at home, interviewers will work alone without any other household members present or within earshot and with the door to the room closed. All data will be stored in password protected databases and in locked file cabinets. Due to the sensitive nature of some of the questions in the patient interview having to do with alcohol intake, injection drug use, and sexual behaviors, we have obtained a federal Certificate of Confidentiality.

**j. References.**

Alter, M.J., Kruszon-Moran, D., Nainan, O.V., McQuillan, G.M., Gao, F., Moyer, L.A., et al. (1995) *The prevalence of hepatitis C virus in the United States, 1988 through 1994.*

CDC. (1998) Recommendations for prevention and control of hepatitis C virus (HCV) and HCV-related chronic disease. *MMWR 1998 47(RR19):1-39.*

Seef, L.B. (2002) Natural history of chronic hepatitis C. *Hepatology, 2002, 36:S35-46.*

Kim, W.R. (2002) The burden of hepatitis C in the United States. *Hepatology, 2002, 36:S30-34.*

Leigh, J.P., Bowlus, C.L., Leistikow, B.N., & Schenker, M. (2001) Costs of hepatitis C. *Arch Intern Med, 2001 161:2231-2237.*

Alter, M.J., (2002) Prevention of spread of hepatitis C. *Hepatology, 2002, 36:S93-S98.*



# Multnomah County Hepatitis C Virus Registry Study Interview Form

Patient ID: RG3-\_\_\_\_\_

**Interview Date:**          /       /              
                                   M M    D D    Y Y    Y Y

**Qualifying HCV Test Date:**       /       /              
   M M    D D    Y Y    Y Y

1.     Where did you get tested for hepatitis C on \_\_\_/\_\_\_/\_\_\_ (HCV test date)?

- Doctor's office 1 \_\_\_
- Hospital/ER 2 \_\_\_
- Health Department 3 \_\_\_
- HIV/STD clinic 4 \_\_\_
- Needle exchange program 5 \_\_\_
- Correctional facility 6 \_\_\_
- Alcohol/drug treatment program 7 \_\_\_
- Other 8 \_\_\_


Specify Other: \_\_\_\_\_  
   Don't know 9 \_\_\_  
   Don't remember 10 \_\_\_

2.     What were you told about the results of the hepatitis C test that you had on \_\_\_/\_\_\_/\_\_\_ (HCV test date)?

- Positive 1 \_\_\_
- Negative 2 \_\_\_
- Told I needed confirmatory testing 3 \_\_\_
- Don't remember 4 \_\_\_
- Other 5 \_\_\_

Specify Other: \_\_\_\_\_  
   Don't know 9 \_\_\_

3.     Were you ever tested for hepatitis C before this test? 1\_\_\_ Yes    2\_\_\_ No

 if No, go to question 6.

4.     In what year were you first tested for hepatitis C?             (*enter '9's if unknown*)  
   Y    Y    Y    Y

5.     What were the results of your previous HCV test? 1 \_\_\_ Positive    2 \_\_\_ Negative    9 \_\_\_ Don't know


*“Now I am going to ask you some questions about your medical care.”*

6.     Do you have one place where you usually go for your routine medical care?

- Yes, Doctor's Office 1 \_\_\_
- Yes, DOH 2 \_\_\_
- Yes, ER 3 \_\_\_
- Yes, Other 4 \_\_\_

Specify Other: \_\_\_\_\_  
   No 5 \_\_\_

7.     Since you got your hepatitis C test results, have you seen a health care provider about your hepatitis C diagnosis or about your liver? 1 \_\_\_ Yes    2 \_\_\_ No    3 \_\_\_ No, but I have an appointment scheduled

 if No, go to question 10.

 if “No, but has appointment scheduled”, go to question 10.

8. What kinds of providers have you seen for your hepatitis C diagnosis? (*Check all that apply*)

- General Internist/Family Practice Doctor/Primary Care Provider 1 \_\_\_
  - Gastroenterologist 2 \_\_\_
  - Infectious Disease Specialist 3 \_\_\_
  - Naturopath 4 \_\_\_
  - Other 5 \_\_\_
- Specify Other: \_\_\_\_\_
- Don't know 9 \_\_\_



**Go to question 10.**

9. Why haven't you seen a health care provider about your Hepatitis C? (*Check all that apply*)

- Haven't felt sick from hepatitis C 1 \_\_\_
- Can't afford a doctor's visit 2 \_\_\_
- Don't have a regular doctor 3 \_\_\_
- Didn't know/think that hepatitis C could be treated 4 \_\_\_
- Don't feel that treatment is needed 5 \_\_\_
- Didn't know that I had hepatitis C 6 \_\_\_
- Other 7 \_\_\_

Specify Other: \_\_\_\_\_

10. Have you ever had a liver biopsy, that is, removal of a piece of liver tissue?      1 \_\_\_ Yes      2 \_\_\_ No

11. What were you told about the condition of your liver?

- There were no problems with my liver 1 \_\_\_
- That I need further evaluation of my liver 2 \_\_\_
- I have some liver damage 3 \_\_\_
- I have liver failure/cirrhosis 4 \_\_\_
- Nothing 5 \_\_\_
- Don't remember 6 \_\_\_
- Other 7 \_\_\_

Specify Other: \_\_\_\_\_

12. What were you told about your hepatitis C infection?

- That I need further evaluation 1 \_\_\_
- That I need treatment for hepatitis C 2 \_\_\_
- That I don't need any further evaluation or treatment 3 \_\_\_
- I don't remember 4 \_\_\_
- Nothing 5 \_\_\_
- Don't remember 6 \_\_\_
- Other 7 \_\_\_

Specify Other: \_\_\_\_\_

13. Have you ever received medication or other therapy from a healthcare provider for hepatitis C?  
(*Check one*)      1 \_\_\_ Yes      2 \_\_\_ No



**If No, go to question 13B.**

14. What treatments have you received for HCV infection?

<b>1</b> Interferon	<b>8</b> Pegylated Ifn
<b>18</b> Interferon + Ribavirin	<b>19</b> Pegylated Ifn + Ribavirin
<b>23</b> Research Medicine (specify): _____	<b>99</b> Unknown

Use separate entry for each treatment regimen from key above

<b>a) Treatment Code</b> <i>(List corresponding number code from treatment above)</i>	<b>b) Year treatment started</b> <i>(begin with most recent year)</i> <i>99 9999 =unknown )</i> <i>(mm yyyy)</i>	<b>c) Length of treatment (in months)</b> <i>99=unknown</i>	<b>d) Reason for stopping</b> <ol style="list-style-type: none"> <li>1. Completed a full course of treatment</li> <li>2. Stopped due to side effects <i>(List all that apply)</i> <ol style="list-style-type: none"> <li>2.a. Anemia</li> <li>2.b. Psychiatric</li> <li>2.c. Leukopenia</li> <li>2.d. Thrombocytopenia</li> <li>2.e. Thyroid abnormalities</li> </ol> </li> <li>3. MD stopped due to lack of response</li> <li>4. MD stopped medication (reason unknown)</li> <li>5. Worsening of liver disease</li> <li>6. Research medication</li> <li>7. Problems with of insurance</li> <li>8. Didn't want to take medication</li> <li>9. Still taking treatment</li> <li>10. Other <i>(specify):</i> _____</li> <li>99. Unknown</li> </ol>
	M M Y Y Y Y _____	M M _____	
	M M Y Y Y Y _____	M M _____	
	M M Y Y Y Y _____	M M _____	
	M M Y Y Y Y _____	M M _____	
	M M Y Y Y Y _____	M M _____	
	M M Y Y Y Y _____	M M _____	
	M M Y Y Y Y _____	M M _____	

15. If no, what was the reason for not receiving treatment from a healthcare provider for your hepatitis C? (pick one)

- I didn't know that I had hepatitis C 1 \_\_\_
- I haven't seen a healthcare provider about my hepatitis C 2 \_\_\_
- I didn't know there was treatment for hepatitis C 3 \_\_\_
- My physician says I do not need treatment because my disease is too mild 4 \_\_\_
- My physician says I do not need treatment (reason unknown) 5 \_\_\_
- I am concerned/worried about the side effects of the treatment 6 \_\_\_
- The treatment is too expensive/can't afford 7 \_\_\_
- I was told that I have/had a low chance of response 8 \_\_\_
- My disease is too advanced and treatment is not safe/recommended 9 \_\_\_
- I have a health condition that prevents/makes treatment too risky 10 \_\_\_
- My physician says I am not a candidate for treatment because of drug use 11 \_\_\_
- My physician says I am not a candidate for treatment because of alcohol use 12 \_\_\_
- I am awaiting new treatments 13 \_\_\_
- I am scheduled for treatment 16 \_\_\_
- Other 14 \_\_\_
- Specify Other: \_\_\_\_\_
- Don't know 15 \_\_\_

16. Has a healthcare provider made any recommendations to you about drinking alcohol?  
 1 \_\_\_ Yes  
 2 \_\_\_ No  
 3 \_\_\_ Haven't discussed my hepatitis C diagnosis with a healthcare provider
17. Have you decreased or stopped drinking alcohol because of your hepatitis C diagnosis?  
 1 \_\_\_ Yes 2 \_\_\_ No 9 \_\_\_ don't know
18. How many times have you been hospitalized overnight for a condition related to your liver? \_\_\_\_\_ times.
19. The hepatitis A vaccine first became available in 1995 and is given in a two dose series. Have you ever received this vaccine? (Check one) 1 \_\_\_ Yes 2 \_\_\_ No
20. The hepatitis B vaccine has been available for over 10 years and is given in a three dose series. Have you ever received this vaccine? (check one) 1 \_\_\_ Yes 2 \_\_\_ No

**“Now we'll talk about health-related issues other than your liver disease.”**

21. In the past 5 years have you had any of the following conditions? (read list, check all that apply)


1. High blood pressure ( <i>Hypertension</i> )	1 ___ Yes 2 ___ No 9 ___ don't know
2. High Cholesterol or Triglycerides ( <i>Hyperlipidemia</i> )	1 ___ Yes 2 ___ No 9 ___ don't know
3. Diabetes	1 ___ Yes 2 ___ No 9 ___ don't know

22. Have you ever been diagnosed by a medical provider or treated for depression or any other mental health illness?  
 (Check one) 1 \_\_\_ Yes 2 \_\_\_ No 9 \_\_\_ don't know

### RISK FACTOR SECTION

**“In this section, I am going to ask you about possible exposures to blood.”**


<p>23. 23. Have you ever received a transfusion of blood or blood products (e.g. platelets, plasma)?          If yes, 24.</p>	<p>1 ___ Yes 2 ___ No</p> <p>____ _</p> <p>Y Y Y Y</p>
<p>24. 24. What year was it when you first received a transfusion of blood or blood products?</p>	<p>1 ___ Yes 2 ___ No</p> <p>____ _</p> <p>Y Y Y Y</p>
<p>25. 25. Have you ever received clotting factor for a disorder such as hemophilia?          If yes, 26.</p>	<p>1 ___ Yes 2 ___ No</p> <p>____ _</p> <p>Y Y Y Y</p>
<p>26. 26. What year was it when you first received clotting factor?</p>	<p>1 ___ Yes 2 ___ No</p> <p>____ _</p> <p>Y Y Y Y</p>
<p>27. 27. Have you ever undergone hemodialysis for kidney failure?          28. If yes, What year was it when you first had hemodialysis?</p>	<p>1 ___ Yes 2 ___ No</p> <p>____ _</p> <p>Y Y Y Y</p>
<p>29. 29. Have you ever been employed in a medical or dental position involving contact with human blood?          If yes, 30-32.</p>	<p>1 ___ Yes 2 ___ No</p>
<p>30. 30. What kinds of medical or dental jobs have you held?</p>	<p>(Check all that apply)          Doctor ___ Nurse ___ Phlebotomist ___ EMT ___          Dentist ___ Dental Hygienist ___          Laboratory worker ___ Dialysis Center employee ___          Other _____</p>
<p>31. 31. What year was it when you were first employed in a position involving contact with blood?</p>	<p>____ _</p> <p>Y Y Y Y</p>
<p>32. 32. Have you ever had an unintentional needle stick injury while on the job?          If yes, 33.</p>	<p>1 ___ Yes 2 ___ No</p>
<p>33. 33. What year was it the first time that you had an</p>	<p>____ _</p>

unintentional needle stick?	Y Y Y Y
<b>34.</b> 34. Have you ever been employed as a public safety officer (e.g. fire fighter, police, prison guard)? <b>If yes 35.</b> <b>35.</b> 35. What was the first year that you were employed as a public safety officer?	1__Yes 2__No  Y Y Y Y
<b>36.</b> 36. Were you ever confined in a jail or prison for at least one week? <b>If yes, 37.</b> <b>37.</b> 37. What was the first year that you were detained in a jail or prison?	1__Yes 2__No  Y Y Y Y
<b>38.</b> 38. Did you ever have household contact with someone who had hepatitis C before or during the time that you had contact with them? <b>If yes, 39.</b> <b>39.</b> 39. In what year did you first have contact with this person?	1__Yes 2__No  Y Y Y Y
<b>40.</b> 40. Did you ever have household contact with someone who used needles to inject street drugs before or during the time that you had contact with them? <b>If yes, 41.</b> <b>41.</b> 41. In what year did you first have contact with this person?	1__Yes 2__No  Y Y Y Y
<b>42.</b> 42. Other than marijuana, have you ever used any recreational or "street" drugs in your lifetime? <i>(Check one)</i> .....  <b>if No, go to question 55.</b>	1__Yes 2__No 9__Refused
<b>43.</b> 43. Which of the following recreational or "street" drugs have you ever used? <i>(Check all that apply)</i>	1. __Steroids 2. __Amphetamines (upper, speed, bennies) 3. __Ecstasy (X, rolling) 4. __Methamphetamine (ice, meth, crank) 5. __Heroin 6. __Cocaine 7. __Hash 8. Crack Cocaine (rock) 9. __Cocaine and Heroin together (speedball) 10. __LSD and other hallocisigins 11. __Ketamine (Special K, GHB) 12. __Other (specify) _____ 13. __Refused
<b>44.</b> 44. When was the first time that you used a recreational drug?	Y Y Y Y
<b>45.</b> 45. Have you used a recreational drug in the last 12 months? <b>46.</b> 46. In the last year, how often did you use a recreational drug?	1__Yes 2__No 9__Refused  1__about everyday 2__1-5 times a week 3__1-3 times a month
<b>47.</b> 47. Have you ever injected or "shot up" a recreational drug? <i>(Check one)</i> ..... <b>48.</b> 48. In what year did you first inject a recreational drug? <b>49.</b> 49. In what year did you last inject a recreational drug?	1__Yes 2__No 9__Refused  Y Y Y Y  Y Y Y Y

<p><b>50.</b> 50. Have you ever used a needle that was used by someone else (including your significant other) before you used it? (Check one) 1 ___Yes 2 ___No 9 ___Can't remember/Refused</p> <p><b>51.</b> 51. Have you ever let someone use your needle (including your significant other) after you used it?</p> <p><b>52.</b> 52. Have you ever participated in a needle exchange program? (Check one)</p> <p><b>53.</b> 53. If No, Why not?</p>	<p>1 ___Yes 2 ___No 9 ___Can't remember/Refused</p> <p>1 ___Yes 2 ___No 9 ___Can't remember/Refused</p> <p>1. ___ Didn't know there one 2. ___ Didn't have transportation to get there 3. ___ I was afraid of the cops 6. ___ Other (specify) _____ 7. ___ Refused 9. ___ Don't Know</p>
<p><b>54.</b> 54. Have you ever participated in a drug treatment program (for drug use, not for alcohol) such as inpatient rehab or N.A. (Narcotics Anonymous) or a methadone clinic?</p>	<p>1 ___Yes 2 ___No 9 ___Refused</p>

**Interviewer: The next section asks a few questions about sexual behaviors**

**55.** Have you ever had sexual intercourse with a person of the opposite sex?  
(Check one) ..... 1 \_\_\_Yes 2 \_\_\_No 9 \_\_\_Refused

 **if No, go to question 57.**

**56.** What is your best estimate of the total number of persons of the opposite sex that you've had sexual intercourse with in your lifetime?  
\_\_\_\_\_ number of persons  
(999=declined answer; if answer is ≥999 enter 998)

**57.** Have you ever had sexual intercourse with a person of the same sex? **(ASK MEN ONLY)**  
(Check one) ..... 1 \_\_\_Yes 2 \_\_\_No 9 \_\_\_Refused

 **if No, or subject is FEMALE, go to question 59.**

**58.** What is your best estimate of the total number of persons of the same sex with whom you've had sexual intercourse in your lifetime?  
\_\_\_\_\_ number of persons  
(999=declined answer; if answer ≥999 enter 998)

**59.** Before you were diagnosed with hepatitis C, did you ever have sex with someone who had ever used needles to inject recreational street drugs? ..... 1 \_\_\_Yes 2 \_\_\_No 9 \_\_\_Refused

**60.** Before you were diagnosed with hepatitis C, did you ever have sex with someone who had hepatitis C?  
..... 1 \_\_\_Yes 2 \_\_\_No 9 \_\_\_Refused

61. Have you ever been diagnosed by a doctor with any sexually transmitted disease, such as gonorrhea, syphilis, chlamydia or genital herpes? 1 \_\_\_ Yes 2 \_\_\_ No 9 \_\_\_ Refused



if subject is FEMALE, complete questions 62 to 66 .

### Women's Health Questions (female patients only)

62. How many times have you been pregnant? \_\_\_\_\_ (99=refused or don't know, enter 0 if 0)

63. How many children have you given birth to? \_\_\_\_\_ (99=refused or don't know, enter 0 if 0)

64. Did you have any children after your hepatitis C diagnosis? Yes 1 \_\_\_  
No 2 \_\_\_  
Don't know/refused 9 \_\_\_

65. How many of your children were screened for hepatitis C after you learned about your diagnosis? \_\_\_\_\_ (9=refused or don't know, enter 0 if 0)

66. How many have tested positive for HCV? \_\_\_\_\_ (9=refused or don't know, enter 0 if 0)

### Demographics

67. What is your gender?  
(Check one) 1 \_\_\_ Male 2 \_\_\_ Female 3 \_\_\_ Transgender

68. What is the month and year of your date of birth?..... M M / Y Y Y Y

69. Are you of Hispanic or Latino origin?  
(Check one) ..... 1 \_\_\_ Yes 2 \_\_\_ No

70. Please select one or more of the following categories to describe your race:  
(Check all that apply)..... White 1 \_\_\_  
Black or African American 2 \_\_\_  
American Indian or Alaska Native 3 \_\_\_  
Asian 4 \_\_\_  
Native Hawaiian or other Pacific Islander 5 \_\_\_

71. What is your height? \_\_\_ feet \_\_\_ inches

72. What is your current weight? ..... \_\_\_ \_\_\_ \_\_\_ pounds

73. What is the highest grade or year of school you completed?  
(Read if necessary and check one) ..... Never attended school or only attended kindergarten 1 \_\_\_  
Grades 1 through 8 (Elementary) 2 \_\_\_

- Grades 9 through 11 (Some high school) 3 \_\_\_
- Grade 12 or GED (High school graduate) 4 \_\_\_
- College 1 year to 3 years (Some college or technical school) 5 \_\_\_
- College 4 years or more (College graduate) 6 \_\_\_
- Refused 9 \_\_\_

74. Are you medically insured by:

\_\_\_5 RefusedUnknown

- \_\_\_1 Private insurance/HMO/Military
- \_\_\_2 Medicaid
- \_\_\_3 Medicare
- \_\_\_4 Uninsured
- \_\_\_5 Other
- \_\_\_6 refused
- \_\_\_7 don't know

75. What was your total combined household income during the past 12 months from all sources of income, including wages, salaries, pensions, and insurance payments? (Check one)

\$15,000 or less 1 \_\_\_

At least \$30,000, but less than \$50,000 3 \_\_\_

Refused 7 \_\_\_

76. How many people live off of this combined income? \_\_\_\_\_

77. Are you currently or have you been homeless in the last year? 1 \_\_\_ Yes 2 \_\_\_ No 3 \_\_\_ Refused

78. What is your current housing situation?

- (Read if necessary and check one) .....Own home 1 \_\_\_
- Live in apartment 2 \_\_\_
- Transitional housing 3 \_\_\_
- Staying with friends/relatives 4 \_\_\_
- Car 5 \_\_\_
- Other (specify) \_\_\_\_\_ 6 \_\_\_
- Refused 9 \_\_\_

79. How many months in the last year have you lived there? \_\_\_ \_\_\_ (number of months) (9s if unknown)

M M

**Now I would like to ask you some questions about alcohol.**

(Interviewer: Get out Alcohol History Chart)

80. Was there ever a period in your life when you consumed at least one drink per month?

(Check one) .....1 \_\_\_ Yes 2 \_\_\_ No 9 \_\_\_ Refused



**If No, go to question 50.**

**I'd like to start with the year that you first began drinking regularly, meaning at least one drink a month, and work forward to the present.**

81. Please think about the first year that you began to have at least one drink per month. How old were you?

*Record the age to one decimal point on the answer sheet.*

Now think to when your drinking behavior was different in a significant way from this time. This could be the next six months or perhaps 2 or 5 years later. Bear in mind any events in your life that changed that may have altered your drinking habits.

*Fill in the age ranges for each stage under the "Age Range" column*

*(Establish when the person's drinking behavior first changed in a significant way from that recorded under First Stage. Since the drinking history is aimed at major trends, some judgment will be necessary in differentiating important from minor changes in drinking patterns.)*

Now that we've established these periods in your life, I'd like to ask you some specific questions about your drinking history. We'll start with the period that you first began drinking regularly and work forward to the present. Please give me information as accurately as you can about what type of beverage you were drinking, how much, and how often.

**82.** *(Show Drink Size cue cards)*

How many drinks would you have on a typical drinking occasion (drinking day)? Please look at the drink sizes on these cards to determine (the equivalent of) how many drinks of this size you would have per day.

*Record the typical number of drinks next to "# of drinks" in the "Quantity" column.*

**83.** How many days per month would you generally drink at this level?

*Record the number of days next to "# of days" in the "Frequency" column.*

**84** What is the most or maximum number of drinks you would have in any one drinking occasion?

*Record the number of drinks next to "maximum" in the "Quantity" column*

*Note: this is the maximum number that the person actually would drink, not an estimate of his/her potential capacity.*

**85.** How many days per month would you generally drink at this level?

*Record the number of days next to "maximum" in the "Frequency" column.*

**86.** What type of beverage would you usually consume in a typical month?

*Record the relative percentages of beer, liquor or wine in the "Type" column*

*(This section should add up to 100%)*

Now think to when you were \_\_\_\_ years old (*the next drinking period*).

*Repeat 54B-F for each period*

**87.** Have you ever been arrested for driving under the influence of alcohol?


*(Check one).....1\_\_\_Yes 2\_\_\_No 9\_\_\_Refused*

**A. 88. Have you ever participated in an alcohol abuse treatment program?**

*(Check one).....1\_\_\_Yes 2\_\_\_No 9\_\_\_Refused*

**89. Are you currently drinking alcohol?**

*(Check one).....1\_\_\_Yes 2\_\_\_No 3\_\_\_Don't know 9\_\_\_Refused*

 **If no, don't know, or refused, go to question 97 of the main questionnaire**

**90. Men:** Considering all types of alcoholic beverages, how many times during the past month did you have 5 or more drinks on an occasion? *(9s if unknown)* \_\_\_\_\_

OR

**91. Women:** Considering all types of alcoholic beverages, how many times during the past month did you have 4 or more drinks on an occasion? *(9s if unknown)* \_\_\_\_\_

92. How many times did you drive after drinking during the past 30 days? (9s if unknown) \_\_\_\_

93. Have you felt that you should cut down on your drinking?  
(Check one).....1 \_\_\_ Yes 2 \_\_\_ No 3 \_\_\_ Don't know 9 \_\_\_ Refused

94. Have people annoyed you by criticizing your drinking?  
(Check one).....1 \_\_\_ Yes 2 \_\_\_ No 3 \_\_\_ Don't know 9 \_\_\_ Refused

95. Have you felt bad or guilty by your drinking?  
(Check one).....1 \_\_\_ Yes 2 \_\_\_ No 3 \_\_\_ Don't know 9 \_\_\_ Refused

96. Have you had a morning eye-opener?  
(Check one).....1 \_\_\_ Yes 2 \_\_\_ No 3 \_\_\_ Don't know 9 \_\_\_ Refused

**Closing Statement: Okay, that's the last question of the survey. Thank you very much for your time.**

97. Are there any questions you would like to ask?

98. Would you like any educational materials about the liver?

(Check one) 1 \_\_\_ Yes 2 \_\_\_ No

99. May we contact you in the future about participating in other research projects related to hepatitis C?

(Record answer and contact information on detachable cover sheet.)

100. Notes \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

The following 2 questionnaires will be handed out to subjects, who will be asked to complete them on their own.

Subject ID: RG3- \_ \_ \_ \_

### Beck Depression Inventory

Choose one statement from among the group of four statements in each question that best describes how you have been feeling during the **past few days**. Circle the number beside your choice.

1	<p><b>0</b> I do not feel sad.</p> <p><b>1</b> I feel sad.</p> <p><b>2</b> I am sad all the time and I can't snap out of it.</p> <p><b>3</b> I am so sad or unhappy that I can't stand it.</p>	8	<p><b>0</b> I don't feel I am any worse than anybody else.</p> <p><b>1</b> I am critical of myself for my weaknesses or mistakes.</p> <p><b>2</b> I blame myself all the time for my faults.</p> <p><b>3</b> I blame myself for everything bad that happens.</p>
2	<p><b>0</b> I am not particularly discouraged about the future.</p> <p><b>1</b> I feel discouraged about the future.</p> <p><b>2</b> I feel I have nothing to look forward to.</p> <p><b>3</b> I feel that the future is hopeless and that things cannot improve.</p>	9	<p><b>0</b> I don't have any thoughts of killing myself.</p> <p><b>1</b> I have thoughts of killing myself, but I would not carry them out.</p> <p><b>2</b> I would like to kill myself.</p> <p><b>3</b> I would kill myself if I had the chance.</p>
3	<p><b>0</b> I do not feel like a failure.</p> <p><b>1</b> I feel I have failed more than the average person.</p> <p><b>2</b> As I look back on my life, all I can see is a lot of failure.</p> <p><b>3</b> I feel I am a complete failure as a person.</p>	10	<p><b>0</b> I don't cry any more than usual.</p> <p><b>1</b> I cry more now than I used to.</p> <p><b>2</b> I cry all the time now.</p> <p><b>3</b> I used to be able to cry, but now I can't cry even though I want to.</p>
4	<p><b>0</b> I get as much satisfaction out of things as I used to.</p> <p><b>1</b> I don't enjoy things the way I used to.</p> <p><b>2</b> I don't get any real satisfaction out of anything anymore.</p> <p><b>3</b> I am dissatisfied or bored with everything.</p>	11	<p><b>0</b> I am no more irritated by things than I ever am.</p> <p><b>1</b> I am slightly more irritated now than usual.</p> <p><b>2</b> I am quite annoyed or irritated a good deal of the time.</p> <p><b>3</b> I feel irritated all the time now.</p>
5	<p><b>0</b> I don't feel particularly guilty.</p> <p><b>1</b> I feel guilty a good part of the time.</p> <p><b>2</b> I feel quite guilty most of the time.</p> <p><b>3</b> I feel guilty all of the time.</p>	12	<p><b>0</b> I have not lost interest in other people.</p> <p><b>1</b> I am less interested in other people than I used to be.</p> <p><b>2</b> I have lost most of my interest in other people.</p> <p><b>3</b> I have lost all of my interest in other people.</p>
6	<p><b>0</b> I don't feel I am being punished.</p> <p><b>1</b> I feel I may be punished.</p> <p><b>2</b> I expect to be punished.</p> <p><b>3</b> I feel I am being punished.</p>	13	<p><b>0</b> I make decisions about as well as I ever could.</p> <p><b>1</b> I put off making decisions more than I used to.</p> <p><b>2</b> I have greater difficulty in making decisions than before.</p> <p><b>3</b> I can't make decisions at all anymore.</p>
7	<p><b>0</b> I don't feel disappointed in myself.</p> <p><b>1</b> I am disappointed in myself.</p> <p><b>2</b> I am disgusted with myself.</p> <p><b>3</b> I hate myself.</p>	14	<p><b>0</b> I don't feel that I look any worse than I used to.</p> <p><b>1</b> I am worried that I am looking old or unattractive.</p> <p><b>2</b> I feel that there are permanent changes in my appearance that make me look unattractive.</p> <p><b>3</b> I believe that I look ugly.</p>

15	<p><b>0</b> I can work about as well as before.</p> <p><b>1</b> It takes an extra effort to get started at doing something.</p> <p><b>2</b> I have to push myself very hard to do anything.</p> <p><b>3</b> I can't do any work at all.</p>	19	<p><b>0</b> I haven't lost much weight, if any, lately.</p> <p><b>1</b> I have lost more than five pounds.</p> <p><b>2</b> I have lost more than ten pounds.</p> <p><b>3</b> I have lost more than fifteen pounds. (Score 0 if you have been purposely trying to lose weight.)</p>
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16	<p><b>0</b> I can sleep as well as usual.  <b>1</b> I don't sleep as well as I used to.  <b>2</b> I wake up 1-2 hours earlier than usual and find it hard to get back to sleep.  <b>3</b> I wake up several hours earlier than I used to and cannot get back to sleep.</p>	20	<p><b>0</b> I am no more worried about my health than usual.  <b>1</b> I am worried about physical problems such as aches and pains, or upset stomach, or constipation.  <b>2</b> I am very worried about physical problems, and it's hard to think of much else.  <b>3</b> I am so worried about my physical problems that I cannot think about anything else.</p>
17	<p><b>0</b> I don't get more tired than usual.  <b>1</b> I get tired more easily than I used to.  <b>2</b> I get tired from doing almost anything.  <b>3</b> I am too tired to do anything.</p>	21	<p><b>0</b> I have not noticed any recent change in my interest in sex.  <b>1</b> I am less interested in sex than I used to be.  <b>2</b> I am much less interested in sex now.  <b>3</b> I have lost interest in sex completely.</p>
18	<p><b>0</b> My appetite is no worse than usual.  <b>1</b> My appetite is not as good as it used to be.  <b>2</b> My appetite is much worse now.  <b>3</b> I have no appetite at all anymore.</p>		

Primary Care Mood Disorders Questionnaire

1. Has there ever been a period of time when you were not your usual self and (while not using drugs or alcohol)		
...you felt so good or so hyper that other people thought you were not your normal self, or you were so hyper that you got into trouble? (please circle yes or no for each line)	Yes	No
...you were so irritable that you shouted at people or started fights or arguments?	Yes	No
...you felt much more self-confident than usual?	Yes	No
...you got much less sleep than usual and found you didn't really miss it?	Yes	No
...you were much more talkative or spoke faster than usual:	Yes	No
...thoughts raced through your head or you couldn't slow your mind down?	Yes	No
...you had much more energy than usual?	Yes	No
...you were much more active or did many more things than usual?	Yes	No
...you were much more social or outgoing than usual; for example, you telephoned friends in the middle of the night?	Yes	No
...you were much more interested in sex than usual?	Yes	No
...you did things that were unusual for you or that other people might have thought were excessive, foolish, or risky?	Yes	No
...spending money got you or your family into trouble	Yes	No
2. If you checked YES to more than one of the above, have several of these ever happened during the <i>same period of time</i> ?	Yes	No
3. How much of a problem did any of these cause you—like being unable to work; having family, money or legal troubles; getting into arguments or fights?  No problem    Minor problem    Moderate problem    Serious problem		
4. Draw a line connecting any blood relative to any problem (this doesn't have to be neat):  Grandparents    Parents    Aunts/Uncles    Brothers/sisters    Children  Suicide    Alcohol/drug problems    Mental Hospital    Depression Problems    Manic/bipolar		
5. Has a health professional ever told you that you have manic – depressive illness or bipolar disorder?	Yes	No

**Attachment 2: Provider Fax to send to all persons reported to Multnomah County Health Department with a positive hepatitis C test.**



**Multnomah County Health Department**

<b>TO:</b>		<b>FROM:</b>	Date:	# of pages	Request	REPLY NEEDED	URGENT
<b>FAX #:</b>		<input type="checkbox"/> Grace Van Ness (503) 988-5090 x24828	Multnomah County Health Department received a report on the referenced individual regarding <b>Hepatitis C</b> (HCV), as required by Oregon State Reporting laws. In accordance with Communicable Disease ordinances we are requesting additional information on the referenced client. You are being contacted as the ordering provider/facility listed by the reporting lab. PLEASE REVIEW THIS REQUEST FOR INFORMATION, COMPLETE AND RETURN TO OUR OFFICE IN A TIMELY MANNER. THANK YOU.				
<b>ATTN:</b>		<input type="checkbox"/> Diata Rhodes (503) 988-5090 x26594					
<b>RE:</b>							
<b>DOB:</b>							
<b>DX:</b>	HEPATITIS C	<b>FAX # 503-988-3407</b>					

Are you the primary care provider for the above referenced individual? <input type="checkbox"/> Yes <input type="checkbox"/> No  Provider: _____  Phone: _____  Specialty: <input type="checkbox"/> IM <input type="checkbox"/> FP <input type="checkbox"/> GI <input type="checkbox"/> Ob/Gyn <input type="checkbox"/> Other (specify) _____  Has this client been notified of lab results? <input type="checkbox"/> Yes <input type="checkbox"/> No  Your diagnosis of HCV infection? <input type="checkbox"/> Acute <input type="checkbox"/> Chronic or resolved <input type="checkbox"/> False + <input type="checkbox"/> Unknown  Has this client been referred to a GI or Hepatologist? <input type="checkbox"/> Yes <input type="checkbox"/> No  Currently or previously received tx? <input type="checkbox"/> Yes <input type="checkbox"/> No  Recommended for tx?	<b>REASON FOR TESTING</b> (please check all that apply)	<b>Risk Factors for HCV Infection</b>
	<input type="checkbox"/> History of HCV infection <input type="checkbox"/> Symptoms of liver disease/hepatitis <input type="checkbox"/> Evaluation of abnormal liver enzyme test <input type="checkbox"/> Screening (asymptomatic) <input type="checkbox"/> Client requested testing <input type="checkbox"/> Client has risk factors for HCV infection <input type="checkbox"/> Other risk factor _____ (please see risk factor section)	<input type="checkbox"/> Hx of IVDU <input type="checkbox"/> Hx of incarceration <input type="checkbox"/> Received transfusion or transplant prior to 1992 <input type="checkbox"/> Received clotting factor prior to 1987 <input type="checkbox"/> Hx of dialysis <input type="checkbox"/> Hx of multiple sexual partners <input type="checkbox"/> Public safety worker <input type="checkbox"/> Medical/Dental worker Was this an occupational exposure? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> UNK <input type="checkbox"/> Other risk factor _____
	Has client been provided education/literature or counseling regarding	

Yes  No  Under evaluation  
Does this patient have cirrhosis?  
 Yes  No  Under evaluation  
**May we contact client?**  Yes  No  
May we forward literature to your client?  
 Yes  No  
Current contact information:  
Address:  
\_\_\_\_\_  
\_\_\_\_\_  
Phone:  
\_\_\_\_\_

HCV?  
 Yes  No  
  
Hep A and Hep B vaccination status?  
Hepatitis A vaccine:  Yes  No  
 Hx of HAV  
Hepatitis B vaccine:  Yes  No  
 Hx of HBV  
Is client insured?  Yes  No

**DEMOGRAPHICS**  
**THIS INFORMATION IS REQUESTED BY OREGON HEALTH DIVISION AND CENTERS FOR DISEASE CONTROL AND PREVENTION : Please Specify:**  
**Ethnicity:**  Hispanic  Non-Hispanic  
**Race:**  White  Black  Asian/Pacific Islander  
 American Indian/Alaska Native  UNK  
  
Other: \_\_\_\_\_  
\_\_\_\_\_  
**Country of Origin:**  US   
Other: \_\_\_\_\_  
**Language:**  ENG   
Other: \_\_\_\_\_  
**Occupation:** \_\_\_\_\_  
\_\_\_\_\_



# Multnomah County Health Department

*Healthy People in Healthy Communities*

Date

Fax:

Dear DOC:

Multnomah County Health Department (MCHD) is conducting a study of County residents with hepatitis C virus (HCV) infection. The purpose of the study is to get information to guide local hepatitis C prevention and treatment activities. **This study involves an interview and medical record review only. This study is NOT a hepatitis C treatment trial.**

Our records indicate that your patient NAME, DOB recently tested positive for hepatitis C. This information was reported to MCHD by the laboratory that performed the test, in accordance with Oregon statute requiring licensed laboratories to report positive test results for hepatitis C (*Oregon Administrative Rule 333-18-00015.*). Additionally, the Health Insurance Portability and Accountability Act (HIPAA) ALLOWS this information to be reported to public health authorities (*see <http://aspe.hhs.gov/admnsimp/PL104191.htm>, Section 1178 (b)*).

We would like to contact this patient to participate in our study. In order to do this in the safest and most appropriate way, we seek to verify that this patient knows the results of his/her hepatitis C test before we attempt any contact.

## **ACTION REQUESTED**

Please...

Check the box(es) below and fax to Diata Rhodes at 503-988-3407 **IF** participation in a one-hour interview would be harmful to this NAME, DOB in the following ways:

- Name, DOB does not know their hepatitis C testing results, and there are **NO** future plans to provide hepatitis C test results to this patient.
- Name, DOB is deceased.
- Name, DOB has a physical/psychiatric condition that would interfere with their ability to participate in a 1 hour interview (e.g. hepatic encephalopathy).

**If we do not hear from you by \_\_\_/\_\_\_/\_\_\_ (four weeks from FAX DATE), we will consider that as an implicit assent and will attempt to contact PATIENT NAME to enroll him/her in the study.**

If participation is not harmful to Name, DOB, please give page 2 of this correspondence to your administrator to verify your patient's current contact information.

If you have any questions about the study, or would like to see the patient questionnaire or the medical record review form, please feel free to contact me at 503-988-5090 x 26594.

Thank you in advance for your assistance.

Diata Rhodes, MA  
Multnomah County HCV Registry Study Research Analyst



# Multnomah County Health Department

*Healthy People in Healthy Communities*

Disease Control Office  
426 SW Stark, 3<sup>rd</sup> floor  
Portland, OR 97204  
503-988-3406 (voice)  
503-988-3407 (fax)

Date  
Fax:

Dear Administrator:

Multnomah County Health Department (MCHD) is conducting a study of County residents with hepatitis C virus (HCV) infection. The purpose of the study is to get information to guide local hepatitis C prevention and treatment activities.

Dr. Name has agreed to allow us to contact Name, DOB to participate in our study. We would like to verify this individual's contact information before we attempt to recruit them into our study. This information was reported to MCHD by the laboratory that performed the test, in accordance with Oregon statute requiring licensed laboratories to report positive test results for hepatitis C (*Oregon Administrative Rule 333-18-00015*). Additionally, the Health Insurance Portability and Accountability Act (HIPAA) **ALLOWS** this information to be reported to public health authorities (*see <http://aspe.hhs.gov/admsimp/PL104191.htm>, Section 1178 (b)*).

According to our records, Name, DOB's current contact information is the following:

**Address:** Address and/or "No Address on File"  
City State Zip Code

**Phone Number:** Phone Number and/or "No Telephone Number on File"

If this information is incorrect, please cross out the address and update the information below and fax to Diata Rhodes at 503-988-3407.

### 3. Patient's current address and/or phone number

**Address:** \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Phone Number:** \_\_\_\_\_

HIPAA ALLOWS the patient's address and phone number to be reported to public health authorities.

Thank you in advance for your assistance.

Diata Rhodes, MA  
Multnomah County HCV Registry Study Research Analyst

Disease Control Office  
426 SW Stark, 3<sup>rd</sup> floor  
Portland, OR 97204  
503-988-3406 (voice)  
503-988-3407 (fax)

**Phone Number:** \_\_\_\_\_

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date



# Multnomah County Health Department

*Healthy People in Healthy Communities*

Attachment 4A—Letter to Potential Subjects

**Reading level: 7.9**

## **Multnomah County, Oregon Hepatitis C Virus Registry Study (MCHRS)**

Date:

Patient Name

Address

Address

Dear \_\_\_\_\_,

Multnomah County Health Department, Oregon Health Services and the Centers for Disease Control and Prevention are doing a study of hepatitis C. You may want to be in the study. We have included a brochure about the study.

In Oregon, labs report the results of hepatitis tests to the health department. These reports are kept private to the extent allowed by law. The health department uses this information to try to control the spread of hepatitis.

The county received a report that you had a hepatitis C test. You should discuss your results with your health care provider. If you have not done so yet, you should before deciding if you are interested in this study. If you decide to take part in the study, you may receive up to \$50 for your time and trouble.

If you know your test results and want to learn more about the study, please call me at 503-988-5090 x. If I cannot answer the phone, you may leave a message telling me how to reach you.

Sincerely,

Diata Rhodes

**Attachment 4B--Second letter (for potential subjects who have not responded to the initial letter or telephone calls)**

Reading level: 8.0



# Multnomah County Health Department

*Healthy People in Healthy Communities*

---

Date

Patient Name

Address

City state zip

Dear \_\_\_\_\_,

We recently sent you an invitation to participate in a hepatitis study. We have also tried to reach you by phone. Since it has been hard to reach you, we are trying a second time to ask if you would like to be in the study. If you take part in the study, we will interview you now and then again in a few years.

We have enclosed a consent form, a survey, and a self-addressed stamped envelope. You will be reimbursed \$25 for your time and trouble to fill out the survey and mail it to us.

If you have questions, please call **503-988-5090 x 26594** between the hours of 8 am to 5 pm Monday-Friday. If I cannot answer the phone, you may leave a message telling me how to reach you, and whether you give permission for us to leave you a phone message.

Sincerely,

Diata Rhodes

Attachment 4C—Response Card and Self-Addressed Stamped Envelope.

This is enclosed in the initial patent letter (Attachment 4A)

Response Card:

**The Multnomah County Hepatitis C Registry Study**

- Yes, I am interested in learning more about this study\_\_\_\_\_
- Contact me at this phone number: \_\_\_\_\_
- No, I am not interested in participating in this study

Name \_\_\_\_\_

Return envelope:



426 SW Stark, 3<sup>rd</sup> floor  
Mailcode: 160/3  
Portland, OR 97204  
Attn: Diata Rhodes

## Attachment 5A—Telephone Script

### The Multnomah County Liver Study Script for Telephone Contact with Potential Study Participants Who Did Not Receive a Letter in the Mail (because no patient address was available)

If answering machine is reached: This is a message for -----(patient name). You have been selected to participate in a health study. This is not a sales call. You will be paid up to \$50 for your time and trouble. You can choose not to take part, but if you want to be in the study or have any questions or concerns, please call Diata Rhodes at 503-988-5090 x 26594. Thank you. Script for Telephone Contact with Potential Study Participants

OR, if patient answers:

**1. MCHD staff:** Hello, may I speak to \_\_\_\_\_ (individual 's name)?

**2. Individual:** No, he/she is not here right now (MCHD staff states that they will try back another time without leaving a message or giving information about what the call is regarding)

*Or:* Yes, this is he/she.

**3. MCHD staff:** This is \_\_\_\_\_(name of staff member). I work for Multnomah County Health Department. The Health Department is doing a special study on hepatitis. I want to talk with you to see if you are eligible to participate in our study. When your health care provider orders a hepatitis test, the laboratory doing the test routinely reports results to the health department. We recently received a report that you had some hepatitis testing done. I'd like to see if you know the results of your hepatitis test. If you do, I'd like to see if you are interested in taking part in the study.

**3. Individual:** Yes, I know the result (skip to 5).

*Or, if No or Not Sure:*

**4. MCHD staff:** It's important for people to know the results of their medical tests. It would be a good idea for you to talk to your health care provider where the test was done about your hepatitis test results. If you think you might want to be in a study about hepatitis after you talk to your provider, please call me back at this number, 503-988-5090 x 26594. If your test wasn't done by a provider that you regularly see or that you can't afford to go see again, we would be able to provide you with your test results and provide you with a list of community agencies that may be helpful to you. (NOTE: in this case, study staff would provide individual post-test counseling, answer questions, and arrange to give the patient a list of local community agencies, and close the conversation. Study staff will NOT attempt to recruit the patient to enroll into the study during this time. Study staff will follow up with individual approximately two weeks after this encounter to ascertain the individual's interest in enrolling into the study.

**5. MCHD staff:** Would you like me to explain more about what the study involves?

**6. Individual:** Yes/No

**7. MCHD staff:** If No response: Is now inconvenient? May I call you at a better time? (Time to recall is arranged. Or if individual does not want to participate at this point, he or she is assured that they will not be contacted again about this study. They are thanked for their time and the conversation is closed)

*Or, if Yes response:* Do you have a few minutes now?

**8. Individual:** Yes

**9. MCHD staff:** The study involves a one-time meeting lasting approximately 45 minutes with you here at the Multnomah County Health Department. During the meeting I will ask you a series of about 65 questions related to hepatitis C. Some of the questions will be about your health – such as current and past illnesses, medications, mental health treatment, health insurance and medical services. Other questions will be about jobs you have had, and your health practices including alcohol and drug use, and sexual activity. I will need you to read a consent form that explains the study and risks and benefits, and sign your consent. You would be reimbursed \$50 for your time and travel expenses. Does this sound like something you might be interested in taking part in?

**10. Individual:** Yes (appointment is arranged for an interview at the MCHD health department)

*Or:* Yes, I'm interested in participating, but I am not able to come to the MCHD health department for the interview (reasons include transportation problems, inability to miss work, child care difficulties, too ill to leave home, etc.)

**11. MCHD staff:** I understand. I have another option if you'd like to consider this. We can do it some other place if you like, such as your home or workplace, and you would still receive \$50 for your time and travel expenses. Or, we could do a telephone interview. It would take about the same amount of time, 45 minutes, and we would reimburse you \$25 for your time to do the interview. How does this sound?

**12. Individual:** Yes, I could do that (arrangements are made for an agreed time and place for the individual and the MCHD staff to meet, or the individual agrees to do a telephone interview).

*Or:* No, I don't want to take part.

The individual is assured that they will not be contacted again about this study, and they are thanked for their time and the conversation is closed.

**If the individual would like to do a telephone interview:**

**13. MCHD staff:** That's great. Do you have time to do the interview now, or would you prefer to do it another time?

**14. Individual:** I have time to do it now. (Skip to #15)

*Or:* I can't do it now, but I could do it another time (MCHD staff arranges a time for the interview to take place)

**15. MCHD staff:** That's fine. I'll start by reading you the study consent form. You can stop me at any time if you don't understand something or want me to go over it again. Then, I'll mail you a copy to sign and return to my office in a self-addressed, stamped envelope (see consent, Attachment 6).

## Attachment 5B—Telephone Script

### The Multnomah County Liver Study

#### Script for Telephone Contact with Potential Study Participants Who Were Already Mailed a Letter About the Study

If answering machine is reached: “This message is for (first name). You have been selected to participate in a health study. This is not a sales call. You may remember receiving a letter about it. If you decide to participate, you will be paid up to \$50 for your time and trouble. You choose not to take part, but if you want to be in the study or have any questions or concerns, please call Diata Rhodes at 503-988-5090 x 26594. Thank you.

#### Script for Telephone Contact with Potential Study Participants

OR, if patient answers: Script for Telephone Contact with Potential Study Participants

**1. MCHD staff:** Hello, may I speak to \_\_\_\_\_ (individual 's name)?

**2. Individual:** No, he/she is not here right now (MCHD staff states that they will try back another time without leaving a message or giving information about what the call is regarding)

*Or:* Yes, this is he/she.

**3. MCHD staff:** This is \_\_\_\_\_(name of staff member). I work for Multnomah County Health Department. This is (name of staff member). I am calling about a letter and brochure you received a couple weeks ago about a research study. Do you remember receiving it in the mail?

**4.Individual:** "Yes" (If Yes, skip to # 6)

Or, if "No" or "I don't know"

**5. MCHD staff:** Well, maybe we got the wrong address or you didn't get it for some other reason. I would like to talk to you a little bit about the study to see if you may be interested in taking part. (Proceed to #6)

**6. MCHD Staff:** The Health Department is doing a special study on hepatitis. I want to talk with you to see if you are eligible to participate in our study. When your health care provider orders a hepatitis test, the laboratory doing the test routinely reports results to the health department. We recently received a report that you had some hepatitis testing done. I'd like to see if you know the results of your hepatitis test. If you do, I'd like to see if you are interested in taking part in the study.

**7. Individual:** Yes, I know the result (skip to 9).

*Or,* if No or Not Sure:

**8. MCHD staff:** It's important for people to know the results of their medical tests. It would be a good idea for you to talk to your health care provider where the test was done about your hepatitis test results. If you think you might want to be in a study about hepatitis after you talk to your provider,

please call me back at this number, 503-988-5090 x 26594 If your test wasn't done by a provider that you regularly see or that you can't afford to go see again, we would be able to provide you with your test results and provide you with a list of community agencies that may be helpful to you. (NOTE: in this case, study staff would provide individual post-test counseling, answer questions, and arrange to give the patient a list of local community agencies, and close the conversation. Study staff will NOT attempt to recruit the patient to enroll into the study during this time. Study staff will follow up with individual approximately two weeks after this encounter to ascertain the individual's interest in enrolling into the study.

**9. MCHD staff:** Would you like me to explain more about what the study involves?

**10. Individual:** Yes/No

**11. MCHD staff:** (if No response) Is now inconvenient? May I call you at a better time? (time to recall is arranged. Or if individual does not want to participate at this point, he or she is assured that they will not be contacted again about this study. They are thanked for their time and the conversation is closed)

*Or, if Yes response:* Do you have a few minutes now?

**12. Individual:** Yes

**13. MCHD staff:** The study involves a one-time meeting lasting approximately 45 minutes with you here at the Multnomah County Health Department. During the meeting I will ask you a series of ~~about~~ 65 questions related to hepatitis C. Some of the questions will be about your health – such as current and past illnesses, medications, mental health treatment, health insurance and medical services. Other questions will be about jobs you have had, and your health practices including alcohol and drug use, and sexual activity. I will need you to read a consent form that explains the study and risks and benefits, and sign your consent. You would be reimbursed \$50 for your time and travel expenses. Does this sound like something you might be interested in taking part in?

**14. Individual:** Yes (appointment is arranged for an interview at the MCHD health department)

*Or:* Yes, I'm interested in participating, but I am not able to come to the MCHD health department for the interview (reasons include transportation problems, inability to miss work, child care difficulties, too ill to leave home, etc.)

**15. MCHD staff:** I understand. I have another option if you'd like to consider this. We can do it some other place if you like, such as your home or workplace, and you would still receive \$50 for your time and travel expenses. Or, we could do a telephone interview. It would take about the same amount of time, 45 minutes, and we would reimburse you \$25 for your time to do the interview. How does this sound?

**16. Individual:** Yes, I could do that (arrangements are made for an agreed time and place for the individual and the MCHD staff to meet, or the individual agrees to do a telephone interview).

*Or:* No, I don't want to take part.

The individual is assured that they will not be contacted again about this study, and they are thanked for their time and the conversation is closed.

**If the individual would like to do a telephone interview:**

**17. MCHD staff:** That's great. Do you have time to do the interview now, or would you prefer to do it another time?

**18. Individual:** I have time to do it now. (Skip to #17)

*Or:* I can't do it now, but I could do it another time (MCHD staff arranges a time for the interview to take place)

**17. MCHD staff:** That's fine. I'll start by reading you the study consent form. You can stop me at any time if you don't understand something or want me to go over it again. Then, I'll mail you a copy to sign and return to my office in a self-addressed, stamped envelope (see consent, Attachment 6).

**Attachment 6: Patient Consent Form**  
**Revised consent form: Approved by DHS IRB 5/5/2005**

**Multnomah County Health Department**  
**In Collaboration with the Centers for Disease Control & Prevention**  
**and Oregon Health Services**

Adult Consent form (18 years of age and older)

---

**PURPOSE**

This is a research study being done by the Multnomah County Health Department, Oregon Health Services and the Centers for Disease Control and Prevention. We are doing this study to learn more about hepatitis C. Hepatitis C is caused by a virus. It infects the liver. It can damage your liver. It can cause serious illness and death. We want to learn more about how hepatitis C is passed from person to person. We also want to learn more about the health problems that people with hepatitis C have and what kind of services they need.

Health department records show that you tested positive for hepatitis C. You may be able to be in our study. We will interview each person who takes part in this study. The interview will last about 45 minutes. About 20-25 people will take part in this study each month.

**CONFIDENTIALITY**

All answers that you give will be kept private. This is so because this study has been given a Certificate of Confidentiality. This means anything you tell us will not have to be given out to anyone, even if a court orders us to do so, unless you say it's okay. But under the 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."

To protect your privacy, we will not put your name on any study records. We will use a study ID number instead of your name on all study records. All study records will be stored in locked files. Only study staff will be allowed to look at them. Study forms will not have your name on them. Your name will NOT be in any publication of the study results.

We will not share any information about you with your insurance company, your employer or anyone else. We will do everything we can to protect your privacy. If someone outside the study were to see your study records, it is possible that your answers to some of the interview questions could affect your ability to get a job or health insurance.

**PROCEDURES**

If you decide to be in the study, we will do an interview. In the interview, we will ask you about your illnesses, medicines, health insurance, medical services you use, mental health treatment, work, alcohol and drug use, and sexual health. Some of the questions are sensitive. You may refuse to answer any question for any reason. We can do the interview in person or by phone.

You will have the chance to ask our staff about all types of hepatitis. You will be given information about hepatitis C and hepatitis C services.

We may be interested in talking with you again in 2-5 years to find out about your health. You can refuse to be in future studies and still be in the study we're doing now. If it is okay for us to contact you in the future, we will ask you to give us the names of people who will know how to find you.

## **RISKS AND BENEFITS**

**Risks:** The questions will take about 45 minutes. Some of them may seem very personal or embarrassing. They may upset you. You do not have to answer any of the questions that you do not wish to answer. We will do everything we can to protect your privacy. However, if someone outside the study were to see your study records, it is possible that your answers to some of the questions could affect your ability to get a job or health insurance.

**Benefits:** Being in the study will not help you directly.

Being in the study will provide more information about hepatitis C to doctors and may help other people with hepatitis C in Multnomah County.

## **IN THE EVENT OF HARM/INJURY**

If you feel that you have been harmed by taking part in this study or if you have any questions about your rights as research subject, you can call Dr. Gary Oxman at Multnomah County Department of Health at 503-988-3674

## **COMPENSATION**

You will receive \$25 for taking the time to do the interview, either in person, by phone, or complete and mail a written questionnaire to MCHD. If you do the interview in person, you will receive an additional \$25. There are no costs to you for being in the study.

## **STATEMENT OF PARTICIPATION**

I have been told what will be done as part of this study. I have been told the possible good and bad (benefits and risks) that could happen if I am in this study. I have been told that I do not have to be in the study and I will still get the usual services from the County. I agree to be in this study. I have been told that I can stop being in the study at any time, and I will still get the usual services from the County.

I may contact Grace Van Ness at 503-988-5090 x 24828 or Diata Rhodes at 503-988-5090 x 26594 at any time if I have questions about the study.

I have read the above and choose to join the study

## **FUTURE STUDIES**

- I am willing
- I am NOT willing

**To be contacted by the Multnomah County Health Department for future studies.**

---

**Signature**

**Date**

---

**Print Name**

## **Attachment 6B: Telephone Consent Form**

**The reading level of the interviewer's dialogue in the telephone script Attachment 6B is 8.0.**

### **The Multnomah County Hepatitis C Registry Study (MCHCRS)**

#### *Script for Telephone Interviews with Study Participants*

This script is to be used after the potential participant has already been contacted and has initially agreed to participate by a telephone interview at a pre-arranged time. The research staff will call the individual and use the following script to obtain verbal consent prior to beginning the questionnaire.

**Research staff:** "Hello, Mr. /Ms. (individual's name). This is (name of staff member) of the Multnomah County Health Department. Is this a good time for you to talk?"

**Individual:** "Yes. I can talk now."  
"No, I can't talk now." (Alternative arrangements are made).

**Research Staff:** "Ok, before we start, I want to remind you that if you decide to take part in this study, I will ask you about your medical history and how you may have gotten hepatitis. I will ask some questions about drugs and sex. It's probably best if you're alone while we talk. Is it ok for us to keep talking?"

**Individual:** "Yes. It's okay for me to talk now."  
"Well, no, I can't talk now." (Alternative arrangements are made).

**Research staff:** "First, I would like to explain more about this research study. This research study is being done by the Multnomah County Health Department, Oregon Health Services and the Centers for Disease Control and Prevention."

We are doing this study to learn more about hepatitis C. Hepatitis C is caused by a virus. It infects the liver. It can damage your liver. It can cause serious illness and death. We want to learn more about how hepatitis C is passed from person to person. We also want to learn more about the health problems that people with hepatitis C have and what kind of services they need.

Health department records show that you tested positive for hepatitis C. You may be able to be in our study. We will interview each person who takes part in this study. The interview will last about 45 minutes.. About 20 to 25-people will take part in this study each month.

"Do you have any questions at this point about hepatitis C or why we want to do this study?"

**Individual:** "No, I understand."  
OR: "Yes, I'd like to ask you about..."

**Research Staff:** "In order to decide whether or not you wish to be a part of this research study you should know enough about its risks and benefits to make an informed decision. We will discuss this

now over the phone. Once you understand the study, you will be asked if you want to be in the study. Your verbal answer will indicate if you want to be part of the study or not. That way, we can do the questionnaire today. If you decide to be in the study, we will also mail you a written consent form for you sign and mail back to us in a self-addressed stamped envelope. We will mail you a copy of this form for you to keep in the future if you have questions about the study.”

“All answers that you give will be kept private. This is so because this study has been given a Certificate of Confidentiality. This means anything you tell us will not have to be given out to anyone, even if a court orders us to do so, unless you say it’s okay. But under the 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.”

“To protect your privacy, we will not put your name on any study records. We will use a study ID number instead of your name on all study records. All study records will be stored in locked files. Only study staff will be allowed to look at them. Study forms will not have your name on them. Your name will NOT be in any publication of the study results. We will not share any information with your insurance company, your employer or anyone else. We will do everything we can to protect your privacy. However, if someone outside the study were to see your study records, it is possible that your answers to some of the interview questions could affect you ability to get a job or health insurance.”

“Do you have any questions about the steps we are taking to protect your privacy for this study?”

**Individual:** "No, I understand."

OR: "Yes, I'd like to ask you about..." (research staff addresses questions, and asks if okay to proceed to next section)

If you decide to be in the study, we will do an interview. In the interview, we will ask you about your illnesses, medicines, health insurance, medical services you use, mental health treatment, work, alcohol and drug use, and sexual health. Some of the questions are sensitive. You may refuse to answer any question for any reason. We can do the interview in person or by phone.

You will have the chance to ask our staff about all types of hepatitis. You will be given information about hepatitis C and hepatitis C services.

“We may be interested in talking with you again in 2-5 years to find out about your health. You can refuse to be in future studies and still be in the study we’re doing now.” If it is okay for us to contact you in the future, we will ask you to give us the names of people who will know how to find you.

"Do you have any questions about how the study works?"

**Individual:** "No, I understand."

OR: "Yes, I'd like to ask you about..." (research staff addresses questions, and asks if okay to proceed to next section)

**Research staff:** “The questions will take about 45 minutes. Some of them may seem very personal or embarrassing. They may upset you. Some of your answers to the questions could affect your ability

to get a job or health insurance if someone outside the study found out. You do not have to answer any of the questions that you do not wish to answer. Being in the study will not help you directly. Being in the study will provide more information about hepatitis C to doctors and may help other people with hepatitis C in Multnomah County.”

“Do you have any questions about the risks or benefits of this study?”

**Individual:** "No, I understand."

OR: "Yes, I'd like to ask you about..." (research staff addresses questions, and asks if okay to proceed to next section)

**Research Staff:** “You will receive a one-time payment of \$25 for taking the time to do the interview over the phone. If you do the interview in person, you will receive an additional \$25 for your transportation costs. There are no costs to you for being in the study.”

“Do you have any questions about your reimbursement for being in our study?”

**Individual:** "No, I understand."

OR: "Yes, I'd like to ask you about..." (research staff addresses questions, and asks if okay to proceed to next section)

**Research Staff:** “Based on what we have talked about, you can refuse to take part in this study. Choosing not to take part in the study will not affect the services that you can get from the County. You can leave the study at any time that you want by notifying Grace Van Ness, MPH at 503-988-5090, extension 24828. Leaving the study will not affect the services that you can get from the County.”

““If you have questions about your rights as a research subject or think that you have been harmed by taking part in the study, you can call Dr. Gary Oxman, Health Officer for Multnomah County at 503-988-3674.”

“Do you understand that you can refuse to be in the study, and it will not affect the services you get from Multnomah County?”

**Individual:** "Yes, I understand."

OR: "No, I'd like to ask you about..." (research staff addresses questions, and asks if okay to proceed to next section)

**Research Staff:** “Do you have any questions about who to call if you have questions about this study?”

**Individual:** "No, I understand."

OR: “I'd like to ask you about..." (research staff addresses questions, and asks if okay to proceed to next section)

**Research Staff:** “As I said earlier, your verbal answer will indicate if you want to be part of the study or not. Do you give your consent to participate in the project that I've described to you?”

**Individual:** "Yes, I will participate."  
OR: "No, I will not participate."

**Research Staff (if consent is given):** "I am recording that you have given verbal consent to participate in the Multnomah County Hepatitis C Registry Study on this date. Now we will begin the questionnaire."

**Research Staff (if consent is not given):** "Well thank you for your time. I want to remind you that refusing to be in the study will not affect your ability to access services at Multnomah County in the future. Do you have any further questions?"

Individual "Yes" (research staff addresses questions, and closes conversation appropriately)

OR "No." Research staff thanks individual for their time, and closes conversation appropriately.

**At the conclusion of the questionnaire, the research staff will obtain the individual's preferred mailing address to mail the reimbursement check for participation in the study, answer any additional questions the individual may have, thank the individual for participating, and close the conversation appropriately.**