MEDICAL RECORD	CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY • Adult Patient or • Parent, for Minor Patient

INSTITUTE: National Institute of Diabetes and Digestive and Kidney Diseases

STUDY NUMBER: 91-DK-0214 PRINCIPAL INVESTIGATOR: T. Jake Liang, M.D.

STUDY TITLE: Evaluation of Patients with Liver Disease

Continuing Review Approved by the IRB on 11/29/11
Amendment Approved by the IRB on 1/31/12 (R) Date Posted to Web: 2/9/12
Standard

INTRODUCTION

We invite you to take part in a research study at the National Institutes of Health (NIH).

First, we want you to know that:

Taking part in NIH research is entirely voluntary.

You may choose not to take part, or you may withdraw from the study at any time. In either case, you will not lose any benefits to which you are otherwise entitled. However, to receive care at the NIH, you must be taking part in a study or be under evaluation for study participation.

You may receive no benefit from taking part. The research may give us knowledge that may help people in the future.

Second, some people have personal, religious or ethical beliefs that may limit the kinds of medical or research treatments they would want to receive (such as blood transfusions). If you have such beliefs, please discuss them with your NIH doctors or research team before you agree to the study.

Now we will describe this research study. Before you decide to take part, please take as much time as you need to ask any questions and discuss this study with anyone at NIH, or with family, friends or your personal physician or other health professional.

As a patient with liver disease, you are invited to participate in this research study, which will evaluate patients like yourself in a careful and thorough manner to gain insight into the natural history of your disease and to provide a better understanding of its causes. You will be an outpatient and will visit our clinic regularly. On each visit you will be examined by a physician and will have a blood sample taken for routine liver tests and HIV testing for which a separate consent form would have to be signed by you. On some occasions, we may take extra blood samples for research blood tests related to hepatitis or your liver disease. Samples of your serum will also be kept stored for future testing, and these samples will be labeled with your name. While tests may be done on these samples in the future, these tests will be related to hepatitis or liver disease and not to unrelated conditions. If samples of your blood are sent for testing by outside investigators, they will be sent under code so as to protect your confidentiality.

Initially, and at intervals of 1 to 5 years, you will also undergo an ultrasound examination of the liver in which sound waves are used to measure the size and texture of the liver. If your clinical condition warrants further evaluation, you

may be admitted to the National Institutes of Health (NIH) Clinical Center for a more thorough evaluation and liver biopsy. However, you will be asked to have a liver biopsy only if it is needed for your medical care, and you will be given a separate consent form to sign for the biopsy. Furthermore, you may refuse to have a liver biopsy and still be eligible to continue as an outpatient. If you qualify for one of the research treatment studies being carried out at the NIH, you may be asked to enter that study. In that case, you will have the study explained to you fully and will sign another consent form. You may also be asked to undergo skin biopsy, lymphapheresis and plasmapheresis for research purposes. The purposes and procedures will be explained to you in detail and a separate consent form will be used.

If you do not return for routine outpatient visits, we may try to contact you to return for follow up evaluation or to learn of your medical status. If we are unsuccessful at reaching you and cannot track you through your referring physician or next-of-kin, we may request a computer search of the National Death index which is done by the National Center for Health Statistics. If your name appears on the National Death Index we will request copies of medical records, death certificate and autopsy reports.

Hazards and Discomforts

The only hazards and discomforts of this study are the inconvenience of coming to the NIH outpatient clinic on a regular basis and having frequent blood tests. You will be seen in clinic from 1 to 12 times per year (typically every 4 weeks up to the 48th week), and on each occasion you will have blood taken. While most of the blood tests are part of routine care of your liver disease, we may draw extra samples for research purposes. These extra blood samples for research will be used to test for the cause or nature of your liver condition; they will not be used for testing for unrelated medical conditions or for genetic information. Drawing blood usually causes slight discomfort or pain at the place the needle is inserted in your arm. Occasionally a bruise occurs where the blood is drawn. Some patients faint after blood drawing. No more than 14 ounces (approximately 28 tablespoons) of blood will be drawn during any 6-week period; this is equivalent to a pint of blood, the amount that you would give if you donated blood once at a blood bank.

As part of this study, we will test you for infection with the human immunodeficiency virus (HIV), the virus that causes AIDS. If you are infected with HIV you will still be able to participate in this study. We will tell you what the result mean, how to find care, how to avoid infecting others, how we report newly diagnosed HIV infection, and the importance of informing your partners at possible risk because of your HIV infection.

As part of our study, we are planning to invite you to undergo a fibroscan ultrasound for research purposes and we will ask you to sign a separate consent if you are willing to undergo that research procedure.

You will likely be asked to undergo routine ultrasound examination of the liver if ordered by physician.

The ultrasound examinations of the liver are done in the radiology department. They will be scheduled during the times of your regular visits, and do not have any known hazards or discomforts.

You will be asked to fill out two brief questionnaires regarding your sleep during your clinic visit. The questions will help us to identify sleep disorders and fatigue in patients with chronic liver disease. There are no risks associated with these questionnaires.

Benefits

Most of the tests and procedures that will be done in this study are considered as routine medical care for your condition. Any treatment you receive will be the best available, according to standard medical practice. You may not benefit directly

from participating. However, you will have a complete medical evaluation of your condition, you will be kept informed of the current knowledge about this disease, and you will be eligible to enter research studies of therapy for your liver condition that are conducted at the NIH.

Storage and Disposition of Clinical Samples

Samples of your blood and white blood cells taken during this study will be kept stored in secure locked files or freezers in the Clinical Center of the NIH. Furthermore, information on your medical history and response to treatment will be kept in medical files in the medical record room of the Clinical Center as well as in special research files in the Liver Diseases Branch. The samples will have personal identifiers removed and will be assigned a unique code. These samples and records are stored indefinitely so that they can be analyzed again in the future if new information arises about any type of hepatitis and its treatment or new tests become available that will allow better understanding of your liver condition and response to treatment. The record will be kept confidential and your privacy protected by keeping them in secure and locked places. Serum samples may be sent to Institute of Clinical Chemistry and Pathobiochemistry, RWTH University Hospital, Aachen, Germany for measurement of connective tissue growth factor (CTGF) which is a marker of fibrosis. The samples will be anonymized and coded, and the code file will be maintained by the principal investigator on a password protected, encrypted server. The external collaborators will not have access to personally identifiable information and will not have an influence on the analysis of the results or their reporting. The results of this study will likely be published in the medical literature, but you will not be identified individually and any information about you (like name, age, sex, diseases, current medications, and treatment) will not be released to others. You may request copies of your records at any time and may ask us to destroy your samples held in the Liver Diseases Branch if you so wish.

Conflict of Interest Statement

The National Institutes of Health reviews NIH employees at least yearly for conflict of interest. The following link contains details on this process http://ethics.od.nih.gov/forms/Protocol-Review-Guide/pdf. You may ask your research team for additional information or a copy of the Protocol Review-Guide.

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OTHER PERTINENT INFORMATION

1. Confidentiality. When results of an NIH research study are reported in medical journals or at scientific meetings, the people who take part are not named and identified. In most cases, the NIH will not release any information about your research involvement without your written permission. However, if you sign a release of information form, for example, for an insurance company, the NIH will give the insurance company information from your medical record. This information might affect (either favorably or unfavorably) the willingness of the insurance company to sell you insurance.

The Federal Privacy Act protects the confidentiality of your NIH medical records. However, you should know that the Act allows release of some information from your medical record without your permission, for example, if it is required by the Food and Drug Administration (FDA), members of Congress, law enforcement officials, or authorized hospital accreditation organizations.

2. Policy Regarding Research-Related Injuries. The Clinical Center will provide short-term medical care for any injury resulting from your participation in research here. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the National Institutes of Health, the Clinical Center, or the Federal Government. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.

3. Payments. The amount of payment to research volunteers is guided by the National Institutes of Health policies. In general, patients are not paid for taking part in research studies at the National Institutes of Health. Reimbursement of travel and subsistence will be offered consistent with NIH guidelines.

4. Problems or Questions. If you have any problems or questions about this study, or about your rights as a research participant, or about any research-related injury, contact the Principal Investigator, T. Jake Liang, M.D.; Building 10, Room 9B16, Telephone: 301-496-1721. Other researchers you may call are: Hwalih Han at 301-496-1665.

You may also call the Clinical Center Patient Representative at 301-496-2626.

5. Consent Document. Please keep a copy of this document in case you want to read it again.

COMPLETE APPROPRIATE ITEM(S) BELOW:

A. Adult Patient's Consent

I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I hereby consent to take part in this study.

[redacted] 07.11.2012

Signature of Adult Patient/Legal Representative — Date

[redacted]

Print Name

B. Parent's Permission for Minor Patient.

I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I hereby give permission for my child to take part in this study.
(Attach NIH 2514-2, Minor's Assent, if applicable.)

Signature of Parent(s)/Guardian — Date

Print Name

C. Child's Verbal Assent (If Applicable)

The information in the above consent was described to my child and my child agrees to participate in the study.

Signature of Parent(s)/Guardian — Date — Print Name

THIS CONSENT DOCUMENT HAS BEEN APPROVED FOR USE FROM NOVEMBER 29, 2011 THROUGH NOVEMBER 28, 2012.

[redacted] 7/11/12

Signature of Investigator — Date

[redacted]

Print Name

[redacted] 7-11-12

Signature of Witness — Date

[redacted]

Print Name

PATIENT IDENTIFICATION

[redacted]

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CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY (Continuation Sheet)
· Adult Patient or · Parent, for Minor Patient
NIH-2514-1 (07-09)
P.A.: 09-25-0099
File in Section 4: Protocol Consent