UNIVERSITY OF PENNSYLVANIA

RESEARCH SUBJECT
INFORMED CONSENT AND HIPAA AUTHORIZATION FORM

Protocol Title: A Structural Approach to Bone Disease Due to Hepatitis C

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Why am I being asked to volunteer?

We invite you to take part in this research study. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. This form, called a consent form, tells you about what will happen during the study and the risks and benefits of participating in this study. The form also includes other important information about the research study, including the health information we will collect. The research team is going to talk to you about the research study, and they will give you this consent form to read. You may also decide to discuss it with your family, friends, or family doctor. You may find some of the medical language difficult to understand. If there is anything in this form you do not understand, please ask questions. You do not have to take part in this study if you do not want to. If you take part, you can leave the study at any time. If you decide to participate, you will be asked to sign this form. You will receive a copy of this form if you decide to participate.

You are being invited to take part in a research study to compare bone structure, bone density, and levels of hormones that affect bone calcium levels in patients who have HIV and chronic hepatitis C, chronic hepatitis C alone, and HIV alone. You are being invited to participate in this research study because you are infected with HIV and/or chronic hepatitis C virus infections.

What is the purpose of this research study?

Prior research has shown that hepatitis C virus infection is associated with reduced bone mineral density in HIV-infected women but not men. However,

these results have not yet been replicated, and no studies have compared bone density between patients with HIV and chronic hepatitis C, chronic hepatitis C alone, and HIV alone to determine the effects of each of these chronic infections on bone density. Therefore, the purpose of this study is to examine how bone structure and bone density differ between HIV and chronic hepatitis C-coinfected women receiving combination HIV treatment compared to women with hepatitis alone and women with HIV alone who receive combination HIV treatment. This study involves special techniques which allow us to evaluate the microscopic structure of bone. These new techniques will provide knowledge on the impact of hepatitis C virus infection on bone structure and density in women with HIV and/or chronic hepatitis C virus infections and potentially suggest ways to improve the bone density in women with hepatitis C and/or HIV. This study is supported by a research grant from PENN Center for AIDS Research.

How long will I be in the study? How many other people will be in the study?

The study involves one visit that should last about 90 minutes. We expect a total of 150 women to be enrolled (50 HIV/chronic hepatitis-coinfected women, 50 women with chronic hepatitis C alone, and 50 women with HIV only).

What am I being asked to do?

If you choose to participate, you will visit The Children's Hospital of Philadelphia (CHOP) Clinical Translational Research Center on only one occasion to answer some questions on your health and to gather information about your bone structure and density. We will also ask you to provide blood samples. All of the procedures are conducted for research purposes and will take place at the CHOP Clinical Translational Research Center. These procedures will take approximately 1½ hours. If you agree to take part in this study, you will have the following tests and procedures, which are described below:

Medical History, Medications, Alcohol, and Physical Activity: We will ask you questions about your medical history, including medications you currently take. We will also ask you questions about your alcohol consumption and physical activity. These questions will require 10 to 30 minutes.

Measures of Body Size: We will measure your height with a wall-mounted stadiometer, weight with a digital scale, and the length of your arm and leg with a tape measure. This takes 5 minutes.

Measures of Bone Density and Size: We will measure the amount of mineral in your bone by a method called dual energy x-ray absorptiometry (DEXA). This is also known as a bone density screening test. This method uses a very low-powered x-ray beam. We will scan the hip, wrist and spine region. We will also scan the entire body to measure muscle and fat. The results of all the scans will then be analyzed in the computer and estimates of bone, fat, and muscle in the body will be obtained. The test is done while you

are lying very still on a tabletop. Each scan takes fewer than 5 minutes. The whole process will take about 30 minutes. The radiation used is very low.

We will also measure the density and size of the bones in the lower left leg and left forearm using a technique called peripheral quantitative computed tomography (pQCT). Like the DEXA machine, this instrument uses a low-energy x-ray beam to measure the density of bone. It is different from the DEXA, however, because it measures the hard outer layer of bone separately from the softer inner layer of bone. The test is done while your foot or arm remains in a still position in the machine. The total time for all of the scans on the pQCT machine will be approximately 20 minutes. The radiation exposure for each scan is very low.

Laboratory Tests: We will collect 3 to 4 teaspoons of blood during the study visit. These samples will be used to measure levels of hormones that affect bone and mineral metabolism, levels of hormones that affect bone strength, levels of markers of inflammation, vitamin D, and parathyroid hormone, a hormone that affects bone calcium levels. A urine pregnancy test will be given before the bone scans in all women who menstruate.

What are the possible risks or discomforts?

Taking part in a research study involves risks or "side effects." You should talk about these risks with the study doctor or your regular doctor. There may be other side effects we do not know about yet. Your health is important to us. We will talk to you if we need to make changes to the study to protect your health. We will also tell you about any new information that may change whether you want to stay in the study.

Blood Work: Taking blood may cause some pain, bleeding or bruising at the spot where the needle enters your body. Rarely, taking blood may cause fainting or infection.

Pregnancy Risks for Females: If you are pregnant or nursing, you should not take part in this research study. Women who know that they are pregnant or who think that they might be pregnant cannot participate in this study due to potential risk of radiation to the fetus. Participants are required to tell the investigator if they might be pregnant. A urine pregnancy test will be given before the bone scans in all women who menstruate. If you are found to be pregnant, you will not be able to continue participation in the study.

DEXA and pQCT Scans: This study involves exposure to radiation from the DEXA and pQCT scans. You will therefore receive a small dose of radiation. This dose is not needed for your medical care. You will get the radiation only because you are taking part in this study. Radiation can increase the risk of cancer after many years but at a dose much higher than you will receive. Because of the low dose of radiation, it is very likely that you will not see any radiation effects at all.

What information about me may be collected, used or shared with others?

We need to collect health information about you in order to conduct this study. This includes information about you from medical records and from the procedures, interviews, and tests that are part of this research. Routine clinical laboratory tests performed as part of this study will appear in your medical record. We will do our best to keep your personal information private and confidential.

Why is my information being used?

Your information is used by the research team to contact you during the study. Your information and results of tests and procedures are used to: 1) Do the research, 2) Oversee the research, and 3) See if the research was done right.

Who may use and share information about me?

We will use your information for the needs of this study and to evaluate the study results. The following individuals may use or share your information for this research study: the research team, the Hospitals' ethics committees (Institutional Review Board), and CHOP CTRC staff.

Who, outside of the School of Medicine, might receive my information?

Besides the above people at Children's Hospital and the University of Pennsylvania, the Jonathan Lax Treatment Center (Philadelphia FIGHT) is also a participating site in this study. The collaborating researcher from this site may also have access to your information.

The results of this study may be shown at meetings or published in journals so other doctors and health professionals know about the study. We will keep your identity private in any publication or presentation about the study.

The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to University of Pennsylvania procedures developed to protect your privacy.

How long may the School of Medicine use or disclose my personal health information?

Your authorization for use of your personal health information for this specific study does not expire.

Your information may be held in a research database. However, the School of Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization

- The University of Pennsylvania's Institutional Review Board grants permission
- As permitted by law

Can I change my mind about giving permission for use of my information?

Yes. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the investigator for the study to the address provided on page 1 of the consent form. If you withdraw your permission, you will not be able to stay in this study.

What if I decide not to give permission to use and give out my health information?

If you decide not to give permission to use and give out your health information, you will not be able to be in this research study.

You will be given a copy of this Research Subject HIPAA Authorization describing your confidentiality and privacy rights for this study.

By signing this document you are permitting the School of Medicine to use and disclose personal health information collected about you for research purposes as described above.

What if new information becomes available about the study?

During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

What are the possible benefits of the study?

You are not expected to get any benefit from being in this research study. However, upon completion of the study visit and after the bone scans have been reviewed, we will provide you with a report of the DEXA hip and spine scans. You may share the DEXA report with your physician. We hope that what we learn in this study may help us understand bone disease in people with chronic hepatitis C.

What other choices do I have if I do not participate?

The alternative to participation in this study is not to participate. There will be no penalties or loss of benefits to which you are otherwise entitled if you decide not to participate or to withdraw at any time. Your current and future medical care will not be affected if you decide not take part in this study.

Will I be paid for being in this study?

You will receive $50 for your participation in this study. This payment is to reimburse you for expenses related to participating in the study, such as transportation and parking, and to compensate you for the time and inconvenience related to your participation.

Will I have to pay for anything?

All costs of participating in this study will be covered by the study. There are no additional costs to you or your insurance. You and/or your health insurance may be billed for the costs of medical care during this study if these expenses would have happened even if you were not in the study.

What happens if I am injured or hurt during the study?

If you have a medical emergency during the study you should go to the nearest emergency room. You may contact the Principal Investigator or Emergency contact listed on page one of this form. You may also contact your own doctor, or seek treatment outside of the University of Pennsylvania. Be sure to tell the doctor or his/her staff that you are in a research study being conducted at the University of Pennsylvania. Ask them to call the telephone numbers on the first page of this consent form for further instructions or information about your care.

In the event that you are hurt or injured as a result of participation in this research study, please contact the investigator listed on page one of this form.

In the event of any physical injury resulting from research procedures, medical treatment will be provided without cost to you, but financial compensation is not otherwise offered from the University of Pennsylvania. If you have an illness or injury during this research trial that is <u>not</u> directly related to your participation in this study, you and/or your insurance will be responsible for the cost of the medical care of that illness or injury.

When is the Study over? Can I leave the Study before it ends?

This study is expected to end after all participants have completed all visits, and all information has been collected. This study may also be stopped at any time by your physician or the study Sponsor without your consent because:

- The Primary Investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.
- The Sponsor or Principal Investigator has decided to stop the study.

If you decide to participate, you are free to leave the study at anytime. Withdrawal will not interfere with your future care.

Who can see or use my information? How will my personal information be protected?

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Who can I call with questions, complaints or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on page one of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Office of Regulatory Affairs with any question, concerns or complaints at the University of Pennsylvania by calling (215) 898-2614.

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania to disclose that personal health information to outside organizations or people involved with the operations of this study.

A copy of this consent form will be given to you.

_____	_____	
Name of Subject (Please Print)	Signature of Subject	Date

_____	_____	
Name of Person Obtaining Consent (Please Print)	Signature	Date