

University of California, Los Angeles

CONSENT TO PARTICIPATE IN RESEARCH

Substudy in young adults who are infected with HIV versus young adults who are not infected with HIV

Technical title: HIV Replication and Thymopoiesis in Adolescents - Substudy

Consent form for control subjects

Principal Investigator: Paul Krogstad, M.D.

Co Investigators: Martin Anderson, M.D., Yvonne Bryson, M.D., Karin Nielsen, M.D., and Jaime DeVille, M.D.

UCLA Department of Pediatrics, Los Angeles, California

You are asked to participate in a research study conducted by the investigators listed above. You have been asked to participate in this sub-study because you are participating in the main study looking at the function of the thymus, an organ in your body that makes special cells called T cells to fight infections. Your participation in this sub-study is entirely voluntary. You can still participate in the main study even if you decide not to participate in this sub-study. You should read the information below, and ask questions about anything you do not understand, before deciding whether or not to participate.

This study is sponsored by a grant from the National Institutes of Health (NIH).

DISCLOSURE STATEMENT

Your health care provider may be an investigator of this research protocol, and as an investigator, is interested in both your clinical welfare and in the conduct of the study. Before entering in this study, or at any time during the research, you may ask for a second opinion about your care from another doctor who is in no way associated with this project. You are not under any obligation to participate in any research project offered by your physician.

PURPOSE OF THE STUDY

In this sub-study we are looking to see how HIV infection affects the thymus. The thymus is a gland that produces cells that help fight infection. This study will be done by looking at how the thymus functions in young adults who are infected with HIV versus how it functions in young

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adults, like you, who are not infected with HIV. We will do this by using a special sugar solution or special water that contains a chemical (“a label”) that is taken into your cells. We can then detect the label by testing your blood. The first subjects who are in the sub-study will receive a labeled sugar solution. We are not sure if this procedure will allow us to detect enough of the label in your cells. If it doesn’t, the next subjects in the sub-study will receive a special water solution that contains the label. You will receive only the sugar solution or the water solution, not both, and you will be told which you will receive before you start the sub-study.

Your participation in this substudy will last for 1 month. Up to 30 subjects may be enrolled in this substudy, with up to 10 at UCLA.

PROCEDURES

If you volunteer to participate in this study, we would ask you to do the following things:

Month 6

At the month 6 visit of the main study, we would ask you to plan on staying overnight in the hospital for one night. If you will receive the sugar solution, it will be given to you over a 24 hour period through a needle in one of your veins. You will have a drop of blood collected from your fingertip or other similar area at 12 hours and again at 24 hours. You will also be asked to come back to the clinic between 4 and 7 days, and between 8 and 14 days after you receive the sugar solution to have more blood collected (up to 3½tablespoons at each visit, but it may be less depending on your body weight). If you receive the water solution, you will drink about ¼ cup of the water solution three times over at least a 12 hour period while you are at the hospital. If you do not get dizzy or have other reactions from drinking the water, you may be able to go home after 12 hours, however, you must be prepared to stay overnight if that is necessary. You will be asked to give a urine sample at the end of your stay. You will get the water solution to take home with you. Once you go home, you will be asked to drink about ¼ cup of the water solution 3 times a day for four days. After that, you will be asked to drink ¼ cup of the water solution twice a day for the rest of the month. The investigator or a member of the study team will call you during the four week period to remind you to drink the water solution. You will be asked to come back to the clinic once a week for four weeks. Each time you come back to the clinic you will have either a small amount of saliva collected on a small sponge, or you will be asked to give a few drops of urine. At week 2 and week 4 you will have up to 3½tablespoons of blood collected, although it may be less blood depending on your body weight.

The blood and saliva or urine collected in this substudy will be tested to see how the labeled sugar or labeled water enters your cells.

POTENTIAL RISKS AND DISCOMFORTS

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The risks of this study are given below. In addition, there may be risks that are currently unforeseeable.

Infusion of sugar solution

If you are given the sugar solution, you will have a needle in one of your veins for the entire time you're in the hospital. This may cause pain, infection, bruising, swelling at the site and rarely, fainting.

Drinking the water solution

If you are given the water solution to drink, you may be slightly dizzy during the first 24 hours that you drink it. This is because you will be drinking water that has more of the "label" than you are used to.

Blood collection

Blood drawing may produce pain, infection, bruising, swelling at the site and rarely, fainting. When possible, the blood will be drawn at the same time you are having blood drawn for another reason.

ANTICIPATED BENEFITS TO SUBJECTS

You will not benefit from participating in this substudy.

ANTICIPATED BENEFITS TO SOCIETY

This study may help physicians to better understand how HIV decreases the body's ability to fight infections and tailor appropriate therapy for HIV.

ALTERNATIVES TO PARTICIPATION

An alternative is not to participate.

PAYMENT FOR PARTICIPATION

You will be paid \$75 for the overnight stay, \$35 when you come back for the first blood collection, and \$35 when you come back for the second blood collection, for a total of \$145 if you complete all three visits.

POSSIBLE COMMERCIAL PRODUCTS

All tissue and/or fluid samples are important to this research study. Your sample will be owned by the University of California or by a third party designated by the University (such as another university or a private company). If a commercial product is developed from this research

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project, the commercial product will be owned by the University of California or its designee. You will not be paid even if a product is made because of this research.

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SAMPLE REMAINING AT THE END OF THE STUDY

On the checklist at the end of this consent form, you will be asked to indicate if you would permit part of this sample to be shared with other researchers. If you agree to have your sample shared with other researchers and later decide to withdraw, we may not be able to retrieve any or all of your sample from other researchers. The researcher is not required to store your sample(s) indefinitely.

INFORMATION ABOUT YOUR SAMPLE

On the checklist below, you are asked to let us know if you would like to receive information about the results of this study. There are two types of information you may receive:

1. general information about what this study found (or conclusions of the study);
2. specific information about what the study found about your sample.

You may also choose not to receive any information. Research is a long and complicated process. Obtaining general information from a project may take years. Even if there is general information from a project, there may not be personal information for every participant.

FINANCIAL OBLIGATION

Neither you nor your insurance company will be charged for your participation in this research.

PRIVACY AND CONFIDENTIALITY

The only people who will know that you are a research subject are members of the research team and, if appropriate, your physicians and nurses. No information about you, or provided by you during the research, will be disclosed to others without your written permission, except:

- if necessary to protect your rights or welfare (for example, if you are injured and need emergency care); or
- if required by law.

When the results of the research are published or discussed in public, no information will be included that would reveal your identity.

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PARTICIPATION AND WITHDRAWAL

Your participation in this research is VOLUNTARY. If you choose not to participate, that will not affect your relationship with UCLA (or UCLA Medical Center), or your right to health care or other services to which you are otherwise entitled. If you decide to participate, you are free to withdraw your consent and discontinue participation at any time without prejudice to your future care at UCLA.

WITHDRAWAL OF PARTICIPATION BY THE INVESTIGATOR

The investigator may withdraw you from participating in this research if circumstances arise which warrant doing so. The investigator will make the decision and let you know if it is not possible for you to continue. The decision may be made either to protect your health and safety, or because it is part of the research plan that people who develop certain conditions may not continue to participate.

NEW FINDINGS

During the course of the study, you will be informed of any significant new findings (either good or bad), such as changes in the risks or benefits resulting from participation in the research or new alternatives to participation, that might cause you to change your mind about continuing in the study. If new information is provided to you, your consent to continue participating in this study will be re-obtained.

IDENTIFICATION OF INVESTIGATORS

In the event of a research related injury or if you experience an adverse reaction, please immediately contact one of the investigators listed below. If you have any questions about the research, please feel free to contact any of the investigators. They can be reached Monday through Friday, 8:00 AM to 4:30 PM. at the numbers listed below. You may be asked to leave a message with the secretary for the investigator to call you back.

Paul Krogstad, M.D.	[redacted]
Martin Anderson, M.D.	[redacted]
Yvonne Bryson, M.D.	[redacted]
Karin Nielsen, M.D.	[redacted]
Jaime DeVille, M.D.	[redacted]

After hours, or in case of emergency, the investigators can be reached through the UCLA page operator at [redacted].

RIGHTS OF RESEARCH SUBJECTS

You may withdraw your consent at any time and discontinue participation without penalty. You are not waiving any legal claims, rights or remedies because of your participation in this research study. If you have questions regarding your rights as a research subject, you may contact the

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Office for Protection of Research Subjects, 2107 Ueberroth Building, UCLA, Box 951694,
Los Angeles, CA 90095-1694, [redacted]

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SIGNATURE OF RESEARCH SUBJECT

I have read (or someone has read to me) the information provided above. I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction. I have been given a copy of this form, as well as a copy of the Subject's Bill of Rights.

BY SIGNING THIS FORM, I WILLINGLY AGREE TO PARTICIPATE IN THE RESEARCH IT DESCRIBES.

Name of Subject

Signature of Subject

Date

• SHARING OF SAMPLES

Please check the appropriate box below and initial:

_____ I agree to have my tissue/fluid sample shared with other researchers.

_____ I do not want my tissue/fluid sample shared with other researchers.

• INFORMATION ABOUT MY SAMPLE

Please indicate by checking and initialing the category below what type of information you want to receive. It is your responsibility to let the investigator know if your address and/or telephone number changes. The contact information is in this informed consent form under "Identification of Investigators".

_____ General Information about what the study found

_____ Specific Information about what the study found about me

_____ I do not want any information about my sample

SIGNATURE OF INVESTIGATOR

I have explained the research to the subject and answered all of his/her questions. I believe that he/she understands the information described in this document and freely consents to participate.

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Signature of Investigator

Date (must be the same as subject's)

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