

Childrens Hospital Los Angeles
CONSENT TO PARTICIPATE IN RESEARCH

A RESEARCH STUDY TO DETERMINE SAFETY OF AN INVESTIGATIONAL
 NON-INVASIVE BLOOD GLUCOSE MONITOR

Subject's Name:	
CHLA#:	
Birth Date:	

• INTRODUCTION

You are asked to participate in a research study conducted by Mark Borchert, M.D. from the Department of Ophthalmology at Childrens Hospital Los Angeles and the University of Southern California. You have been asked to participate in this study because you are blind in one eye. We would like to study the safety of an experimental glucose-measuring device on that eye. Participation in this study is completely voluntary. Please read the information below, and ask questions about anything you do not understand, before deciding whether or not to participate.

• BACKGROUND AND PURPOSE OF THE STUDY

Currently, to measure the body's glucose (sugar) level, a sample of blood must be taken. Diabetics, for example, must withdraw blood from a finger-stick 4-6 times per day. We have invented a machine that measures glucose inside of the eye, behind the clear cornea, without touching the eye. Glucose inside of the eye changes quickly with changes in blood glucose. Consequently, measurements of glucose inside the eye can be used to calculate blood glucose levels. The device focuses infrared light just inside the front of the eye and measures the light reflected back by glucose from within the eye. This technique is called Raman spectroscopy. Raman spectroscopy has been found to be accurate and safe in rabbit eyes. Before it can be tested for accuracy in humans, we must demonstrate that it does not harm human eyes. The purpose of this study is to determine if Raman spectroscopy for glucose measurement is safe for human eyes that are already blind. Another purpose of the study is to determine how long Raman spectroscopy can be comfortably performed on the eye.

• PROCEDURES

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

You will have a complete examination of your eyes before, and two days after, Raman spectroscopy. This examination will include photographs of different parts of your blind eye taken with specialized cameras. It will also include a fluorescein angiogram of your blind eye. This involves injecting a dye (fluorescein) into a vein in your arm and photographing the dye as it travels through the blood vessels of the eye. Prior to injecting fluorescein, we will withdraw 2 cc. (approximately 1/2 tsp.) of blood to measure glucose. If you have had a fluorescein angiogram within two weeks of the study, we will not repeat it prior to Raman spectroscopy. We will still need to draw blood for glucose measurement prior to Raman spectroscopy. By performing these tests before and after Raman spectroscopy, we will be able to distinguish damage of Raman

spectroscopy from that of pre-existing eye disease. The total time for testing each day will be approximately 1 to 1½ hour.

Following the first eye examination and fluorescein angiography, Raman spectroscopy will be performed on the blind eye. You will lie on your back facing a microscope above your head. The microscope will be advanced slowly to within ½ inch of the eye. In a practice session you will be asked to look at a light outside the microscope for up to 40 seconds with your good eye. Then Raman spectroscopy will be performed on the blind eye. The duration of Raman spectroscopy will be determined based on how long you were able to look into the microscope during the practice session. Raman spectroscopy will be repeated two or three times. You will then be asked to rate any discomfort you had from looking at the light from the Raman spectroscopy.

You will be asked to return in 2-7 days for repeat fluorescein angiography and photographs of your eye, and again in 3-4 months for a brief eye exam and possible photographs.

- **POTENTIAL RISKS AND DISCOMFORTS**

Raman spectroscopy uses pure infrared light focused in the front of the eye. Although it is not expected, it is possible that some subjects may find the light uncomfortable. It is also possible that infrared light focused in the front of the eye can damage the structures of the front of the eye, such as the lens, cornea, or iris. Damage to the lens could cause a cataract to develop that could develop into a white spot in the center of the pupil. Damage to the cornea could cause temporary pain for about a day until the surface of the cornea heals. It could also cause a small white scar on the front surface of the eye. Damage to the iris could cause a microscopic scar. No damage to these structures was seen in animal studies using this instrument at much higher powers than would be used in your eye.

Fluorescein angiography causes nausea in some individuals usually lasting less than 30 seconds. Rarely does it cause vomiting. If fluorescein is instilled into the skin rather than into the vein, it causes pain and swelling of the skin. In severe cases it can cause blisters and scarring. Care will be taken to insure that the intravenous line is not leaking into the skin prior to injecting fluorescein.

- **ANTICIPATED BENEFITS TO SUBJECTS**

There is no direct benefit to you from participation in this study.

- **ANTICIPATED BENEFITS TO SOCIETY**

In the future, this type of technology may reduce the need for diabetics to use needle sticks to withdraw blood for glucose measurements.

- **ALTERNATIVES TO PARTICIPATION**

This study is being done for research purpose only. You have the option of not participating in this study or withdrawing at any time.

- **FINANCIAL OBLIGATION**

This research study is partially funded by the California Institute of Technology – Jet Propulsion Laboratory (JPL). There is no cost to you. You will receive \$75 for each of the first two days of participation in this study and \$25 for the brief visit 3 to 4 months later. You will also be reimbursed for taxi fare to and from your home.

- **EMERGENCY CARE AND COMPENSATION FOR INJURY**

Childrens Hospital Los Angeles and the physician investigators each maintain professional liability insurance to compensate patients for injuries caused by the fault of Hospital employees or physicians. The physicians are not employees or agents of the Hospital and are separately insured. If an injury is not caused by the fault of a Hospital employee or a physician, neither the Hospital nor the physicians provide reimbursement for treatment expenses or other compensation for the injury, and payment for care of such injury will be billed to you and/or your health benefit plan. You are not waiving any legal claims, rights or remedies because of your participation in this research study.

If you believe that physical injury has been suffered as a result of participation in this study, you should contact Dr. Mark S. Borchert at (323) 361-4510. Treatment for such injury will be available under the same financial arrangement as treatment is usually provided.

- **PRIVACY AND CONFIDENTIALITY**

Members of the research team and, if appropriate your physicians and nurses will know that you are a research subject. All results will be kept confidential, but may be made available to you, and/or your physician if you wish. Authorized representatives of the Food and Drug Administration (FDA), the Department of Health and Human Services, and the CHLA Committee on Clinical Investigations (CCI) may need to review records of individual subjects. As a result, they may see your name; but they are bound by rules of confidentiality not to reveal your identity to others. 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 are injured and need emergency care); or
- if required by law (i.e., reports of certain infectious diseases).

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity. If photographs will be used for educational purposes, your identity will be protected or disguised.

- **PARTICIPATION AND WITHDRAWAL**

Your participation in this research is VOLUNTARY. Your choice about whether or not to participate will have no affect your care, services or benefits at Childrens Hospital Los Angeles. If you agree to participate, but later decide to withdraw from the study, you may do so without affecting you or your rights to health care, services or other benefits at Childrens Hospital Los Angeles.

- **HOW TO OBTAIN INFORMATION**

In the event of a research-related injury or if you experience side effects, please immediately contact the investigator listed below.

Daytime, Monday through Friday, 8:00 A.M. through 4:30 P.M. you may call Dr. *Mark Borchert* at (323) 361-4510. You may also call the study coordinator, Dan Spencer, at any time for questions or concerns relating to your participation. His phone number is (323) 361-7608.

Evenings, nights, weekends or holidays you may call the hospital number 323/660-2450 and ask for the Ophthalmology Service doctor on-call.

If your questions are not an emergency, you can obtain better information by calling Dr. Mark Borchert, Monday through Friday, 8:00 a.m. through 4:30 p.m., than by calling Childrens Hospital Los Angeles on call service after hours.

- **FINANCIAL INTEREST OF THE INVESTIGATOR**

Funding for this research study is partially provided by the California Institute of Technology – Jet Propulsion Laboratory (JPL). The funding is used to support the activities of the Division of Ophthalmology and to reimburse the Division for the costs of the study personnel. Compensation is *not based* upon the number of research subjects enrolled. Neither the principal investigator nor the research staff receives a direct financial incentive from your participation in this study.

Dr. Borchert is one of the inventors of this technology and could receive financial benefit in the future from patent revenues. If your physician is an investigator for this study, he is interested in both your healthcare and the conduct of this research. You are not under any obligation to participate in a research study conducted by your doctor.

- **RIGHTS OF RESEARCH SUBJECTS**

You may withdraw your permission to participate 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 CHLA Office for Human Subjects Protections at 323/361-2265.

SIGNATURE OF RESEARCH SUBJECT

Your signature(s) below indicate

- You have read this document and understand its meaning;
- You have had a chance to ask questions and have had these questions answered to your satisfaction;
- You consent to participation in this research study; and
- You will be given a copy of the signed permission form and of the *Experimental Subject's Bill of Rights*.

Name of Subject

Signature of Subject

Date

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 gives permission to participate.

Name of Investigator

Signature of Investigator

Date (must be the same date as subjects)

CHECK THAT THE BILL OF RIGHTS AND SIGNED HIPAA AUTHORIZATION IS OBTAINED.

SIGNATURE OF WITNESS (if applicable)

My signature as witness indicates that the subject voluntarily signed this consent form in my presence.

Name of Witness

Signature of Witness and Date
(must be the same date as subject's)

SIGNATURE OF INTERPRETER (if applicable)

Name of Witness

Signature of Witness and Date
(must be the same date as subject's)

Routing of signed copies of the consent form:

- 1) Give to adult subject.
- 2) Place in the CHLA Medical Record
- 3) Place in the Principal Investigator's research file.

