Please check one of the following:

_____ You are an adult subject in this study.

_____ You are the parent or guardian granting consent for a minor in this study.

Print minor's name here: _____

Are you participating in any other research studies? _____ Yes _____No

INTRODUCTION TO RESEARCH STUDIES

A research study is designed to answer specific questions, sometimes about an assistive device and its effectiveness. Being a subject in a research study is different from being a patient. When you are a patient, you and your personal doctor have a great deal of freedom in making decisions about your health care. When you are a research subject, the Protocol Director and the research staff will follow the rules of the research study (protocol) as closely as possible, without compromising your health.

PURPOSE OF RESEARCH

You are invited to participate in a research study that is an assistive technology course project. Stanford University engineering students will design and develop an assistive device for your use. A total of eight subjects have participated in this study in2004, 2005 and 2006. These projects will occur primarily during the Winter and Spring Quarters January to June of 2008.

You were selected as a possible participant in this study because you need an assistive device and a team of students has been chosen to design and develop one for you. This study will give the students experience in working with individuals with physical disabilities and will allow you to retain the device if completed satisfactorily.

DURATION OF STUDY INVOLVEMENT

If you decide to participate, we will discuss your needs, evaluate your physical abilities, and make you part of the team in the design and development of the device. The length of the project will be one or two quarters – 10 to 20 weeks.

PROCEDURES

Your participation in the project will consist of your attendance at meetings during which the student team will work with you, ask for your advice during the device's design and development as well as test the device as it is being built. The number of meetings will depend on the specific project and will be no more than two per week. The student team

may need to take body measurements and perhaps body casts if the device is to be fitted to your body.

POSSIBLE RISKS, DISCOMFORTS AND INCONVENIENCES

Every effort will be made to make the device as safe and usable as possible. Because it is a new, one-of-a-kind device, there is a chance that it may have shortcomings or inconveniences which are unknown until it is tested and used. Procedures may involve risks to the participant, which are currently unforeseeable.

POTENTIAL BENEFITS

We expect that the device will provide individuals with disabilities with new or improved independence or capabilities.

WE CANNOT AND DO NOT GUARANTEE OR PROMISE THAT YOU WILL RECEIVE ANY BENEFITS FROM THIS PROJECT.

SUBJECT'S RIGHTS

You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction. If you decide not to participate, tell the Protocol Director. You will still receive care for your health conditions and will not lose any benefits to which you would otherwise be entitled.

You will be told if any new information is learned which may affect your condition or influence your willingness to continue participation in this project. One such example is if a new product becomes commercially available at reasonable cost that meets your needs.

While participating in this study, you should not take part in any other research project without approval from all of the investigators. This is to protect you from possible injury arising from extra x-rays, interaction of research drugs, or similar hazards.

ALTERNATIVES

You are free to go to a private assistive technology facility or anyplace else for the assistive technology that is similar to what will be designed and developed by the Stanford University engineering students. You also have the option not to participate in this project.

CONFIDENTIALITY

Any data that may be published in scientific journals will not reveal your identity unless you give specific permission to do so. Subject information may be provided to Federal and regulatory agencies as required. The Food and Drug Administration, for example,

may inspect research records and learn your identity if this project falls within its jurisdiction.

FINANCIAL CONSIDERATIONS

No payment will be provided for participation in this project, including transportation.

Permits for parking on the Stanford University campus will be provided, if necessary. Your medical insurance will not be billed for any costs of the device. The National Collegiate Inventor and Innovators Alliance and the Haas Center may provide financial support for this study.

The research we are doing may result in new products, tests or discoveries. In some instances these may have potential commercial value and may be developed and owned by the investigators, Stanford University and/or others. You would not share in any financial benefits from these products, tests or discoveries.

WITHDRAWL FROM STUDY

Your participation in this study is entirely voluntary. Your decision whether or not to participate will not prejudice you or your medical care. If you wish to participate in this study, you must sign this form. If you decide to participate, you are free to withdraw your consent, including your authorization regarding the use and disclosure of your health information, and to discontinue participation at any time without prejudice to you or effect on your medical care. If you decide to terminate your participation in this study, you should notify David L. Jaffe at 650/892-4464 or dljaffe@stanford.edu.

At the discretion of the protocol director, you may be taken out of this study due to unanticipated circumstances, such as:

- failure to participate as planned
- if the investigators decide that continuation could be harmful to you
- your need for a device that can not be made in the time allowed
- cancellation of the project.

USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION

Authorization to Use Your Health Information for Research Purposes

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

What is the purpose of this research study and how will my health information be utilized in the study?
The purpose of this study is to develop and design assistive devices for people with disabilities. Your health information may be used in scientific and educational publications.

Do I have to sign this authorization form?
You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study. Signing the form is not a condition for receiving any medical care outside the study.

If I sign, can I revoke it or withdraw from the research later?
If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must contact: David L. Jaffe at 650/892-4464.

What Personal Information Will Be Used or Disclosed?
Your health information related to this study may be used or disclosed in connection with this research study, including, but not limited to your type of disability, age, gender, height, weight and functional limitation necessitating assistive technology.

Who May Use or Disclose the Information?
The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Protocol Director David L. Jaffe
- The Student Design Team
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary.

Who May Receive / Use the Information?

The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services
- The National Collegiate Inventor and Innovators Alliance
- Other funding organizations

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

When will my authorization expire?

Your authorization for the use and/or disclosure of your health information will expire September 30, 2010.

_____ _____
Signature of Subject Date

_____
Signature of Authorized Representative

_____
Description of Representative's Authority to Act for Subject

COMPENSATION

All forms of medical diagnosis and treatment -- whether routine or experimental -- involve some risk of injury. In spite of all precautions, you might develop medical complications from participating in this study. If such complications arise, the Protocol Director and the research staff will assist you in obtaining appropriate medical treatment but this study does not provide financial assistance for additional medical or other costs. Additionally, Stanford is not responsible for research and medical care by other institutions or personnel participating in this study. You do not waive any liability rights for personal injury by signing this form.

CONTACT INFORMATION

- Appointment Contact: If you need to change your appointment, please contact David L. Jaffe at 650/892-4464 or dljaffe@stanford.edu.
- Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or

alternative courses of treatment, you should ask the Protocol Director, David L. Jaffe. You may contact him now or later 650/892-4464 or dljaffe@stanford.edu.

- Injury Contact: If you feel being a part of this study has hurt you, please contact the Faculty Sponsor, Drew Nelson at 650/723-2123 or dnelson@stanford.edu.
- Immediate Medical Assistance: If you need immediate assistance with a medical problem, please call 911.
- Independent of the Research Team Contact: If you are not satisfied with the manner in which this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a research study subject, please contact the Stanford Institutional Review Board (IRB) to speak to an informed individual who is independent of the research team at (650)-723-5244 or toll free at 1-866-680-2906. Or write the Stanford IRB, Administrative Panels Office, Stanford University, Stanford, CA 94305-5401.

HUMAN SUBJECTS BILL OF RIGHTS

As a human subject you have the following rights. These rights include but are not limited to the subject's right to:

- be informed of the nature and purpose of the experiment;
- be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- be given a description of any attendant discomforts and risks reasonably to be expected;
- be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
- be given a disclosure of any appropriate alternatives, drugs or devices that might
- be advantageous to the subject, their relative risks and benefits;
- be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should rise;
- be given an opportunity to ask questions concerning the experiment or the procedures involved;
- be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
- be given a copy of the signed and dated consent form;
- and be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

YOUR SIGNATURE INDICATES THAT YOU HAVE READ AND UNDERSTAND THE ABOVE INFORMATION, THAT YOU HAVE DISCUSSED THIS STUDY WITH THE PERSON OBTAINING CONSENT, THAT YOU HAVE DECIDED TO PARTICIPATE BASED ON THE INFORMATION PROVIDED, AND THAT A COPY OF THIS FORM HAS BEEN GIVEN TO YOU.

_____ _____
Signature of Adult Participant Date

_____ _____
Signature of Legally Authorized Representative Date
(Parent, Guardian or Conservator)

_____
Representative's Authority to Act for Subject

_____ _____
Signature of Legally Authorized Representative Date
(Parent, Guardian or Conservator)

_____
Representative's Authority to Act for Subject

Signatures of both parents are requested, unless the person obtaining consent has determined that the other parent is not reasonably available.

Person Obtaining Consent:
I attest that the requirements for informed consent for the medical research project described in this form have been satisfied – that the participant has been provided with the Experimental Subject's Bill of Rights, if appropriate, that I have discussed the research project with the participant and explained to him or her in non-technical terms all of the information contained in this informed consent form, including any risks and adverse reactions that may reasonably be expected to occur. I further certify that I encouraged the participant to ask questions and that all questions asked were answered.

_____ _____
Signature of Person Obtaining Consent Date