

STANFORD UNIVERSITY - Research Consent Form

Protocol Title: Molecular genetic basis of sensorineural hearing loss

Protocol Director: Iris Schrijver

IRB Approval Date: June 20 2006 IRB Expiration Date: June 19, 2007

STANFORD SAMPLE CONSENT FORM

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:

The following information applies to the individual or to his/her minor child. If the subject is a minor, use of "you" refers to "your child".

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 a drug or device's safety and its effectiveness, sometimes about the origin of a disorder. Being 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 of the genetic causes of hearing loss. We hope to learn which genes, and which changes within these genes, contribute to hearing loss. You were selected as a possible subject in this study because you are hearing impaired. We expect to enroll several hundred patients in this study, with 200 patients from Stanford.

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

Version number:

Date:

STANFORD UNIVERSITY - Research Consent Form

Protocol Title: Molecular genetic basis of sensorineural hearing loss

Protocol Director: Iris Schrijver

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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 Dr. Iris Schrijver at 650-7242403.

This research study is looking for many people with hearing loss, nationwide. Stanford University expects to enroll several hundred research study subjects.

DURATION OF STUDY INVOLVEMENT

This research study is expected to take several years; but it will take only a few minutes of active participation by each subject.

PROCEDURES

If you choose to participate, Dr. Schrijver and her research study staff will ask you to donate a blood sample so that DNA can be extracted from the blood cells.

This will only take a few minutes of your time and only a few teaspoons of blood (5-10cc) are required. If a child is fearful, some studies may be possible from a cheek brush sample without a blood draw.

The DNA will allow us to search for the affected gene(s). Our study will go beyond what is currently offered as diagnostic genetic testing. Because we will investigate known and newly discovered genes, this is not a diagnostic test that could be ordered from a diagnostic laboratory.

The DNA will be stored as part of this study and will not be used in other studies which are not related to hearing loss. We may, however, contact you again about future studies that may be of interest to you.

TISSUE SAMPLING FOR GENETIC TESTING, OTHER TESTING, OR BANKING FOR FUTURE RESEARCH

1. Introduction.

Research using tissues or blood is an important way to try to understand human disease and/or the role genes play in disease. You have been given this consent form because the investigators want to include your tissues or blood in a research project, or because they want to save such samples for research. There are several things you should know before allowing your tissues to be studied:

2. Subject Identification.

Your tissues will be logged in (recorded) under your name and a unique

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Protocol Title: Molecular genetic basis of sensorineural hearing loss

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IRB Approval Date: June 20 2006 IRB Expiration Date: June 19, 2007

number will be assigned. The tubes will be labeled with the unique study number so your name will not be known, at any time, by individuals who are not working on this study. Your name or other public identifiers will not be included with any data shared with other investigators.

3. Risks.

Disease testing and genetic research raises certain questions about informing you of any results. Possible risks of knowing results include: anxiety; other psychological distress; and the possibility of insurance and job discrimination. A possible risk of not knowing includes being unaware of the possibility for treatment. These risks can change depending on the results of the research and whether there is a treatment or cure for a particular disorder. Sometimes patients have been required to furnish information from genetic testing for health insurance, life insurance, and/or a job. Donation of tissues for these research purposes is **not genetic testing**. (However, if you are interested in such clinical testing or genetic counseling, you should contact your physician.)

4. Reporting Results To a Subject.

The National Bioethics Advisory Commission recommends that research results only be reported to subjects (1) when they are scientifically valid and confirmed (e.g., performed by a CLIA certified laboratory), (2) when the findings have significant implications for the health of the subject, and (3) when a course of action or treatment is readily available. On the other hand, results from a non-CLIA laboratory may need to be reported to the subject in order to communicate the need for a test by a CLIA laboratory. Implications for family members, as well as the subject, may be important. In addition, even if no current treatment is available, the subject may be able to monitor for future developments.

Even with special precautions, there is no absolute protection against discrimination on the basis of disease or genetic information. For this reason, the investigator will use the results of this study as research only and not include them in your medical record. Generally, you will not be told the results, even if there might be some potential benefit to you.

However, if our study results can be confirmed by a diagnostic laboratory (e.g., performed by a CLIA certified laboratory), or when the findings have significant implications for treatment, or if we find a result that may have

STANFORD UNIVERSITY - Research Consent Form

Protocol Title: Molecular genetic basis of sensorineural hearing loss

Protocol Director: Iris Schrijver

IRB Approval Date: June 20 2006 IRB Expiration Date: June 19, 2007

implications for you and your family members, then we would be able to share the results if you indicate your wish to be informed.

Please circle [yes or no], depending on whether you wish to be told the test results, if available.

5. Right to Withdraw.

You have the right to refuse to allow your tissues to be studied now or saved for future study. You may withdraw from this study at any time. The investigators might retain the identified samples, e.g., as part of your routine clinical care, but not use them for additional research not related to hearing loss.

6. Completion of Your Research.

Upon completion of this research study, the samples will be stored or banked for other research use in the future. However, before the samples would be used for study of any disorder unrelated to hearing loss, you will be contacted and new consent will be requested for such a study prior to the use of your sample. The samples may be used without any identifiers (**no** possibility to link them back to you) if normal controls are required for another study (e.g. in the case a disorder is being studied that you do not have and normal control samples are needed to confirm absence of findings in normal controls).

7. Family Members.

Disease or genetic information from tissue research can sometimes apply to family members. The investigator will **not** provide genetic information about you to your family members, but you may wish to.

8. Follow Up Contacts.

Investigators in this study may try to recontact you in the future. If you are recontacted and want to know what the investigators have learned about your tissue samples, you should understand the following possibilities:

Information may be too sketchy to give you particular details or consequences.

You may be determined to carry a gene for a particular disease that can be treated. You may be determined to carry a gene for a particular disease for which there is no current treatment.

STANFORD UNIVERSITY - Research Consent Form

Protocol Title: Molecular genetic basis of sensorineural hearing loss

Protocol Director: Iris Schrijver

IRB Approval Date: June 20 2006 IRB Expiration Date: June 19, 2007

You carry a gene for a disease and might consider informing relatives that they, too, might carry the gene. Genetic counselors can help sort out the various options in such a case.

9. Use in Commercial Development of Products.

Any tissues you have donated which are used in research 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. However, donors of tissues do not retain any property rights to the materials. Therefore, you would not share in any financial benefits from these products, tests, or discoveries.

SUBJECT'S RESPONSIBILITIES

You should :

- Ask questions as you think of them.
- Tell the Protocol Director or research staff if you change your mind about staying in the study.
- You will have to sign this consent and Authorization form if you want to participate in this research study.

While participating in this research study, you should not take part in any other research project without approval from the Protocol Director. This is to protect you from possible injury arising from such things as extra blood drawing, or other hazards.

WITHDRAWAL FROM STUDY

If you first agree to participate and then you change your mind, you are **free to withdraw** your consent and discontinue your participation at any time. Your decision will not affect your ability to receive medical care for your disease and you will not lose any benefits to which you would otherwise be entitled.

If you withdraw from the study,

- The genetic basis of your hearing loss may not be identified.
- You must contact the Protocol Director directly (Dr. Schrijver, 650-7242403)

The Protocol Director may also withdraw you from the study without your consent for one or more of the following reasons:

Version number:

Date:

STANFORD UNIVERSITY - Research Consent Form

Protocol Title: _ Molecular genetic basis of sensorineural hearing loss _____

Protocol Director: _ Iris Schrijver _____

IRB Approval Date: _ June 20 2006 _____

IRB Expiration Date: _ June 19, 2007 _____

- Failure to follow the instructions of the Protocol Director and/or study staff.
- The Protocol Director decides that continuing your participation could be harmful to you.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

POSSIBLE RISKS, DISCOMFORTS, AND INCONVENIENCES

There are risks, discomforts, and inconveniences associated with any research study. These deserve careful thought. You should talk with the Protocol Director if you have any questions.

- You may experience mild discomfort, lightheadedness, or bruising from a blood draw.

POTENTIAL BENEFITS

Potential benefits include:

- the discovery of the reason for your hearing loss
- the option to inform your children and other potentially affected family members (if you decide to do so), and genetic counseling
- results leading to better diagnostic tests for hearing loss in the future
- better and earlier treatment possibilities.
- **WE CANNOT AND DO NOT GUARANTEE OR PROMISE THAT YOU WILL RECEIVE ANY BENEFITS FROM THIS STUDY.**

ALTERNATIVES

- The alternative is not to participate.

SUBJECT'S RIGHTS

You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction.

Version number:

Date:

STANFORD UNIVERSITY - Research Consent Form

Protocol Title: Molecular genetic basis of sensorineural hearing loss

Protocol Director: Iris Schrijver

IRB Approval Date: June 20 2006

IRB Expiration Date: June 19, 2007

You will still receive care for your disease and will not lose any benefits to which you would otherwise be entitled.

You will be told of any important new information that is learned during the course of this research study, which might affect your condition or your willingness to continue participation in this study.

CONFIDENTIALITY

Your identity will be kept as confidential as possible as required by law. Except as required by law, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier. Your research records may be disclosed outside of Stanford, but in this case, you will be identified only by a unique code number. Information about the code will be kept in a secure location and access limited to research study personnel.

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. However, your identity will not be disclosed.

Patient information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

FINANCIAL CONSIDERATIONS

PAYMENT

- You will not be paid to participate in this research study.

COSTS

- None. The study will pay for the sample collection (blood draw or cheek brush).

CONTACT INFORMATION

- If you have any questions about this **research study**, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director. You may contact Dr. Iris Schrijver at 650-7242403. If you have any additional questions later, Dr. Iris Schrijver at 650-7242403 will be happy to answer them.
- If you think you have experienced a **research-related injury** call Dr. Iris Schrijver at 650-7242403

Version number:

Date:

STANFORD UNIVERSITY - Research Consent Form

Protocol Title: Molecular genetic basis of sensorineural hearing loss

Protocol Director: Iris Schrijver

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IRB Expiration Date: June 19, 2007

- Alternate contact: If you cannot reach the protocol director and you need to speak to someone immediately, then please call Dr. Phyllis Gardner at 650-498-4826
- If you have any questions about your rights as a research subject, you may contact the Administrative Panel on Human Subjects in Medical Research at (650) 723-5244.
- In addition, 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, call toll free at 1-866-680-2906, or write the Stanford IRB, Administrative Panels Office, Stanford University, Stanford, CA 94305-5401.

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 study 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.

EXPERIMENTAL SUBJECT'S 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;

STANFORD UNIVERSITY - Research Consent Form

Protocol Title: Molecular genetic basis of sensorineural hearing loss

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IRB Approval Date: June 20 2006 IRB Expiration Date: June 19, 2007

- 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.

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Protocol Title: Molecular genetic basis of sensorineural hearing loss

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IRB Expiration Date: June 19, 2007

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 Subject

Date

If the study participant is a minor:

Signature of Legally Authorized Representative

Date

Description of Representative's Authority to Act for Subject

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 subject has been provided with the Experimental Subject's Bill of Rights, if appropriate, that I have discussed the research project with the subject 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 subject to ask questions and that all questions asked were answered.

Signature of Person Obtaining Consent

Date

STANFORD UNIVERSITY - Research Consent Form

Protocol Title: Molecular genetic basis of sensorineural hearing loss

Protocol Director: Iris Schrijver

IRB Approval Date: June 20 2006

IRB Expiration Date: June 19, 2007

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? You are invited to participate in a research study of the genetic causes of hearing loss. We hope to learn which genes, and which changes within these genes, contribute to hearing loss. You were selected as a possible subject in this study because you are hearing impaired. We hope to publish the results (without inclusion of your name or other identifiers) in a scientific journal.

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 write to: Dr. Iris Schrijver, 650-724-2403

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 medical record as it pertains to your hearing loss.

Version number:

Date:

STANFORD UNIVERSITY - Research Consent Form

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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 Dr. Iris Schrijver
- 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

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 on December 31, 2050

Signature of Subject

Signature of Legally Authorized Representative

Date

Description of Representative's Authority to Act for Subject