

**Partners HealthCare System
Research Consent Form**

Subject Identification

Template Version Date: June 2005

Protocol Title: Molecular Genetic Analysis of Inherited Kidney Dysfunction

Principal Investigator: Martin R Pollak, M.D.

Site Principal Investigator:

Description of Subject Population: Individuals with kidney dysfunction

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called “subjects.” This term will be used throughout this consent form. If you have any questions about the research or about this form, please ask us. If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a copy of this form to keep.

Why is this research study being done?

This is an additional optional study that we offer to individuals who are already enrolled in our main study. The purpose of the study is to grow fibroblasts (a type of skin cell) from the skin of subjects with inherited kidney disease. You have been asked to participate in this part of the study because we believe that studying cells grown from your skin will help us understand your kidney problem. We hope to establish cell lines (grow the cells in our laboratory) so that we will be able to study the genetic alteration that causes kidney disease. We intend to enroll about 20 participants in this part of our research study. We hope that this study will lead to better understanding of the genetic changes in problems associated with kidney disease. We also hope that the study will ultimately lead to improved treatment of this condition.

How long will I take part in this research study?

It will take less than one day to participate in this study. We will continue to use the cells obtained and your clinical information (but not your personal identifying information) for many years.

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What will happen in this research study?

In order to grow these cells, samples of skin from people with inherited kidney disease are needed. Therefore we would like to obtain a shave biopsy from your skin. Your participation will involve a visit to have a biopsy. For the biopsy, a local anesthetic will be given with a small needle. Then a small piece of skin (2 to 3 millimeters or about 1/8 of an inch across, about the size of the end of a pencil eraser) will be shaved off with a scalpel blade. No sutures (stitches) will be needed. Because a small scar will probably form, most people prefer that skin be taken from the back or the upper outer buttocks. The biopsy will be taken from skin that appears normal.

A cultured cell line will be developed from your skin sample. Cultured cell lines provide an inexhaustible source of your DNA for future research. DNA is the genetic material from which genes are made. It will also provide a cell system for studying the effect of particular gene alterations. The research planned for the cell line will focus specifically on genes responsible for kidney disease. The cell lines will be kept indefinitely by Dr. Pollak and his colleagues.

We may also use these fibroblasts to make a type of cell called an "iPS cell." These cells are a type of stem cell which means that they have the potential to differentiate into different cell types. We plan to develop and study cells that are involved in the kidney and kidney disease specifically. However, these cells will not be used for cloning or to create another living being. These cell lines would also be kept indefinitely by Dr. Pollak and his colleagues.

As with the main part of this study in which you are already enrolled, information obtained by Dr. Pollak and his colleagues from you and/or your medical records will be coded using an alpha-numeric identifier by Dr. Pollak to protect your privacy before it is provided to the other investigators who are conducting this study. Dr. Pollak will maintain a key to the code and keep it in a secure location. The key to the code linking samples to you will remain in control of Dr. Pollak at this hospital and not be released to others. Data from studies of your skin sample and cells cultured from it may be shared with other scientific investigators and may be published in scientific and medical journals and books, but will not contain any information that could identify you as a source of materials for the study.

Your participation in this study, and information produced by this study, will not become part of your medical record. No information that could identify you will be inspected or copied by the study sponsor (and/or its agent), the Food and Drug Administration (FDA), federal or state government agencies. No photographs, audiotapes, or videotapes of you will be taken.

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OPTIONS

It is possible that you may be asked whether you are willing to provide a second skin sample at a later time. Are you willing to be asked? Please check the appropriate answer and initial.

YES: ___ NO: ___ INITIAL ___

It is possible that this research could eventually yield information that is relevant clinically or diagnostically to you or your family. If so, Dr. Pollak may ask whether you would like to know this information and/or whether you would want any clinically relevant information shared directly with your doctor. Before this could occur, you would be asked to sign a separate consent form to authorize any such release of information. Would you like to be told that such information exists, and asked if you would like to know about it? Please check and initial each of the following:

I would like you to share this information with me: YES: ___ NO: ___ INITIAL ___

I would like you to share this information with my doctor: YES: ___ NO: ___ INITIAL ___

Your skin sample and cells cultured from it may be used in the future for research purposes beyond the scope of this study by scientists at outside institutions. No identifying information will link the sample or cultured cells to you. Therefore, information obtained from this research will not be able to be linked to you. Do you agree to this?

YES: ___ NO: ___ INITIAL ___

It is possible that cells cultured from your skin sample may be shared in the future with investigators not associated with this study. Your identity will be unknown to these investigators. Do you agree to this?

YES: ___ NO: ___ INITIAL ___

Cells, tissue, or other specimens removed from you during the course of this study may be valuable for scientific, research, or teaching purposes, or for the development of a new product, which may be distributed commercially. Brigham and Women's Hospital and members of its Professional

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Staff may use your cells, tissue, or other specimens for these purposes. You would not profit from this use.

What are the risks and possible discomforts from being in this research study?

Risks of shave biopsy include brief pain at the biopsy site, bleeding, infection, and a small scar. With any procedure there is always the possibility of unexpected complications, and no guarantee or promises can be made concerning the results of any procedure.

Genetic information from this study does not have medical or treatment implications at this time. However, information about participation in a genetic study may influence insurance and/or employers regarding your health status. Not sharing information about your participation in this study with others will minimize these risks. Information about your participation and results from the study will not be placed in your medical records. Your samples will be coded and the key to the code kept in a separate, locked file.

What are the possible benefits from being in this research study?

Participation in this study is unlikely to be of direct benefit to you. We hope that it will ultimately lead to better understanding of kidney disease, and possibly to development of new treatments. We believe that there will be benefit in the future to patients with kidney disease, as this research may lead to better diagnosis and treatment of kidney disease.

Alternatives

Participation in this study is voluntary and even if you sign this form, you may withdraw your consent at any time. If you decide to withdraw from the study and wish any cell lines derived from your samples to be destroyed, please send a written request to Dr. Martin Pollak, the investigator in charge of the study, at H.I.M. 534, 4 Blackfan Circle, Boston, MA 02115. Please note that if you have agreed to allow samples or cell lines to be used for other purposes, the original identity of this cell line or sample will be removed. In this case we would not be able to identify this part of your sample or cell line.

What treatments or procedures are available for my condition?

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Different forms of kidney dysfunction respond differently to different treatments. For some forms of kidney disease, there are medicines which help the kidney or which slow down the disease process. This particular study is not a test of any treatment. It is a study to uncover the causes of kidney disease. If you do have kidney disease, you should be under the care of an internist and/or nephrologists. If you need us to help you find a doctor to help take care of you, please let us know.

Can I still get medical care within Partners if I don't take part in this research study, or if I stop taking part?

Yes. Your decision won't change the medical care you get within Partners now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. We will tell you if we learn new information that could make you change your mind about taking part in this research study.

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care.

It is possible that we will have to ask you to drop out before you finish the study. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

What will I have to pay for if I take part in this research study?

There will be no cost to you for participation. You may be reimbursed for parking or other travel expenses related to your study visit upon your request.

What happens if I am injured as a result of taking part in this research study?

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if

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appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them.

Giving you care does not mean that Partners hospitals or researchers are at fault, or that there was any wrongdoing. There are no plans for Partners to pay you or give you other compensation for the injury. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the next section of this consent form.

If I have questions or concerns about this research study, who can I call?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Martin Pollak, M.D. is the person in charge of this research study. You can call him/her at 617-525-5840, from M-F 9-5. You can also call Andrea Uscinski at 617-525-5885, M-F 9-5, with questions about this research study.

If you want to speak with someone **not** directly involved in this research study, please contact the Partners Human Research Committee office. You can call them at 617-424-4100.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research

Also, if you feel pressured to take part in this research study, or to continue with it, they want to know and can help.

If I take part in this research study, how will you protect my privacy?

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Federal law requires Partners (Partners HealthCare System and its hospitals, health care providers and researchers) to protect the privacy of health information that identifies you. This information is called Protected Health Information. In the rest of this section, we refer to this simply as “health information.”

If you decide to take part in this research study, your health information may be used within Partners and may be shared with others outside of Partners, as explained below.

We have marked with a how we plan to use and share your health information. If a box is not checked , it means that type of use or sharing is not planned for in this research study.

We will also give you the **Partners Notice for Use and Sharing of Protected Health Information**. The Notice gives more details about how we use and share your health information.

▪ **Health Information About You That Might be Used or Shared During This Research**

- Information from your hospital or office health records within Partners or elsewhere, that may be reasonably related to the conduct and oversight of the research study. If health information is needed from your doctors or hospitals outside Partners, you will be asked to give permission for these records to be sent to researchers within Partners.
- New health information from tests, procedures, visits, interviews, or forms filled out as part of this research study

▪ **Why Health Information About You Might be Used or Shared with Others**

The reasons we might use or share your health information are:

- To do the research described above
- To make sure we do the research according to certain standards - standards set by ethics and law, and by quality groups
- For public health and safety - for example, if we learn new health information that could mean harm to you or others, we may need to report this to a public health or a public safety authority
- For treatment, payment, or health care operations

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■ People and Groups That May Use or Share Your Health Information

1. People or groups within Partners

- Researchers and the staff involved in this research study
- The Partners review board that oversees the research
- Staff within Partners who need the information to do their jobs (such as billing, or for overseeing quality of care or research)

2. People or groups outside Partners

- People or groups that we hire to do certain work for us, such as data storage companies, our insurers, or our lawyers
- Federal and state agencies (such as the U.S. Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, and/or the Office for Human Research Protections) and other U.S. or foreign government bodies, if required by law or involved in overseeing the research
- Organizations that make sure hospital standards are met
- The sponsor(s) of the research study, and people or groups it hires to help perform this research study
- Other researchers and medical centers that are part of this research study
- A group that oversees the data (study information) and safety of this research study
- Other:

Some people or groups who get your health information might not have to follow the same privacy rules that we follow. We share your health information only when we must, and we ask anyone who receives it from us to protect your privacy. However, once your information is shared outside Partners, we cannot promise that it will remain private.

■ Time Period During Which Your Health Information Might be Used or Shared With Others

- Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information.

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▪ Your Privacy Rights

- You have the right **not** to sign this form permitting us to use and share your health information for research. If you don't sign this form, you can't take part in this research study. This is because we need to use the health information of everyone who takes part in this research study.
- You have the right to withdraw your permission for us to use or share your health information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. This includes information used or shared to carry out the research study or to be sure the research is safe and of high quality.

If you withdraw your permission, you cannot continue to take part in this research study.

- You have the right to see and get a copy of your health information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study.

▪ If Research Results Are Published or Used to Teach Others

The results of this research study may be published in a medical book or journal, or used to teach others. However, your name or other identifying information **will not** be used for these purposes without your specific permission.

Consent to take part in this research study, and authorization to use or share your health information for research

Statement of Subject or Person Giving Consent

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other options for treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.

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If you understand the information we have given you, and would like to take part in this research study, and also agree to allow your health information to be used and shared as described above, then please sign below:

Signature of Subject:

Subject

Date/Time

OR

If you understand the information we have given you, and would like to give your permission for the person you are authorized to represent to take part in this research study, and also agree to allow his/her health information to be used and shared as described above, then please sign below:

Signature of Parent(s)/Guardian or Authorized Representative:

Parent(s)/Guardian of Minor

Date/Time

OR

Court-appointed Guardian or Health Care Proxy

Date/Time

OR

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Family Member/Next-of-Kin

Date/Time

Relationship to Subject: _____

Signature of a Witness (when required by the PHRC or by the Sponsor):

Witness (when required)

Date/Time

Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject, and
- I have answered all questions about this research study to the best of my ability.

Study Doctor or Person Obtaining Consent

Date/Time

In certain situations, the Partners Human Research Committee (PHRC) will require that a subject advocate also be involved in the consent process. The subject advocate is a person who looks out for the interests of the study subject. This person is not directly involved in carrying out the research. By signing below, the subject advocate represents (or “says”) that the subject has given meaningful consent to take part in the research study.

Statement of Subject Advocate Witnessing the Consent Process

- I represent that the subject, parent(s), or legally authorized individual signing above has given meaningful consent.

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Subject Advocate
(if required by the PHRC or sponsor for this study)

Date/Time

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