

**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: Healthy adults with no history of 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?

Our team is trying to learn more about what causes disturbances of kidney function, and why this can occur in families. You have been asked to participate in this study because you do NOT have a kidney disorder. We ask healthy individuals to participate so that we can compare the genes of people with kidney disease and those without kidney disease. Genes are small inherited segments of DNA that serve as the instructions for the body to carry out its functions. Variation in genes can account for physical differences between people, and can sometimes have an impact on health. We would like to try to identify gene changes responsible for kidney disease by studying the DNA (genes) in your blood sample and comparing it to the DNA of people with kidney disease.

We expect to include approximately 3500 people in the study.

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IRB Protocol No.: 1999-P-002030 **Sponsor Protocol No.:** N/A
Consent Form Valid Date: 05/12/2009 **IRB Amendment No.:** N/A **Sponsor Amendment No.:** N/A
IRB Expiration Date: 04/20/2010 **IRB Amendment Approval Date:** N/A

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How long will I take part in this research study?

It will take less than one hour to participate in this study. We will continue to use the DNA we will obtain from your blood sample and your clinical information (but not your personal identifying information) for many years.

What will happen in this research study?

If you agree to participate in this study we may ask for a blood sample and/or clinical information in the form of a questionnaire. If we ask for a blood sample, we will draw 4 teaspoonfuls (20 cc's) of your blood. The blood specimen will be sent to Dr. Pollak's laboratory at the Brigham and Women's Hospital in Boston, Massachusetts. From this sample we will perform DNA analyses.

Analyzing the DNA obtained from your blood sample will help us to learn more about the genes that we think are involved in development of kidney disease. Analyzing DNA involves looking at genetic markers and looking at the DNA sequence.

We may decide to develop a cultured cell line from the white blood cells in your blood 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.

In addition to these procedures, we may ask you to complete a brief questionnaire. This questionnaire will have questions regarding your age, race, ethnicity, and health history. You may ask for help from your physicians, nurses, and family members in completing this form. If you wish, you may ask your physician (or other health care provider) to complete the form for you. As with other aspects of this study, all of this information will be kept confidential and is collected only for the purposes of this research study. We may contact you again at a future date to update this information.

These studies will require less than 1 hour to complete. All questions/concerns regarding this study will be answered by Dr. Martin Pollak (617-525-5840) or study coordinator Andrea Uscinski Knob (617-525-5885).

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OPTIONS

Sharing your sample

Your sample/cell line may be used for research purposes unrelated to the study for which it was collected. If so, all identifying information linking the specimen to you will be removed. Information obtained from this research will not be able to be linked to you. It is possible that your sample and/or cell line will be shared with investigators not associated with this project. If so, your identity will be unknown to these researchers. Information regarding research results done by other investigators will not be shared with the investigators of this study.

Do you agree to this? Please check the appropriate answer and initial.

YES ___ NO ___ INITIAL ____

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

This procedure involves very little risk or discomfort. Drawing blood usually causes some pain at the site of the needle and occasionally bruising at the site. Rarely people faint when their blood is drawn. There are no risks associated with urine collections.

Genetic information from this study does not have medical or treatment implications at this time. Information about participation in a genetic study may influence insurance and/or employers impression of 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?

There is no direct benefit to you from this study. However, your participation may help us to learn more about the genetics of kidney disease. 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.

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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.

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.

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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 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 R. Pollak, M.D. is the person in charge of this research study. You can call him at 617-525-5840, from M-F 9-5. You can also call Andrea L. Uscinski Knob, M.S., the genetic counselor and research coordinator, 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.

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

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

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- 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

■ 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

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- 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.

▪ 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

Family Member/Next-of-Kin Date/Time

Relationship to Subject: _____

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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.

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

Date/Time

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