

Partners HealthCare System Research Consent Form

Subject Identification

General Template
Version Date: December 2008

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 & family members

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. Taking part in this research study is up to you. 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 signed copy of this form to keep.

Some of the people who are eligible to take part in this study may not be able to give consent to take part because of their medical condition. Instead we will ask the person’s authorized representative to give consent. Throughout the consent form, “you” always refers to the person who takes part in the study.

Some of the people who are eligible to take part in this study may not be able to give consent because they are less than 18 years of age (a minor). Instead we will ask their parent(s) to give permission for them to take part in the study and will ask them to agree (give their assent) to take part. Throughout the consent form, “you” always refers to the person who takes part in the study.

Subject Population: Individuals with kidney dysfunction & family members

IRB Protocol No.: 1999P002030

Sponsor Protocol No.: N/A

Consent Form Valid Date: 05/20/2009

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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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 have a kidney disorder or are a member of a family with a kidney disorder. This condition can occur without symptoms or over time can result in kidney failure. It may be familial, that is passed from generation to generation in the genes. 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 try to find the gene change responsible for kidney conditions by determining if you are affected and by analyzing the DNA (genes) in your blood sample.

We expect to include approximately 3000 people in this study.

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 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, a urine sample, and/or clinical information in the form of a questionnaire. Sometimes we may also measure your blood pressure. 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 may determine certain mineral concentrations as well as BUN and creatinine levels (which helps us estimate kidney function) and we will perform DNA analyses. A urine specimen may also be obtained to help assess kidney function. We may repeat the urine test to verify the initial results.

In some rare instances we may ask that an ultrasound of the stomach region (including kidneys) be performed. We would only ask for clinical reasons such as to help us to confirm a diagnosis. This ultrasound test is a sound wave picture of the organs in the stomach area and is similar to the ultrasound test performed on pregnant women. This test does not involve the use of needles but

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consists of moving an ultrasound probe across your abdomen while pictures are observed on a television screen and recorded on videotape. (After analysis, the videotape will either be destroyed or retained in Dr. Pollak's laboratory. The videotapes will not be used for any purpose other than evaluation of kidneys of subject members by the investigators.) Any ultrasound will be covered by the study and neither you nor your insurance company will be responsible for paying for this procedure.

DNA obtained from your blood sample will be used to help us identify genes underlying the development of kidney disease. This 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 will ask you to complete a questionnaire regarding clinical information that may be important in helping us understand the kidney problem in you or your family member(s). 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 day 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).

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

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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 ___

Informing other family members about the study

You may be asked if you are willing to inform other family members about this study. If you agree to contact family members, you will inform them that information about this study can be learned from Dr. Pollak. You should not actively recruit or solicit their participation. If a relative is interested, you should inform that person to call Dr. Pollak or you should obtain permission for Dr. Pollak to call him or her. Information regarding participation of family members will be kept private by the investigator.

Receiving results

The genetic testing done in our lab is done on a research basis only. We cannot guarantee results in a particular time frame, and we do not perform genetic testing to facilitate decisions in your immediate clinical care. Anyone requiring a clinical genetic test result should contact their doctor to learn more about clinical genetic testing from a separate CLIA approved testing facility that may be able to offer those services.

However, it is possible that results come out of your participation in our study, and we can let you or your physician know upon your request. If you were not known to have the disease before the blood test was done, it might show that you are affected or that you are at risk of developing kidney disease. You may decide whether or not you want to receive any potential results. We do not share your results with anyone without your permission, including your doctor or other family members.

In the event that a genetic marker for this disease is defined, you or other family members may wish to be studied and counseled by a geneticist. If this occurs, you will need to sign a separate consent form to authorize the release of any information. Genetic counseling can be arranged through your local physician or by Andrea Uscinski. Andrea is a genetic counselor at Brigham and Women's Hospital and the study coordinator and can assist in counseling (617-525-5885) or in

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identifying clinical geneticists near your home. All reagents and information necessary for analyses would be made available to appropriate institutions by Dr. Martin Pollak.

Please let us know if you would like us to contact you and/or your doctor in the event that relevant information is learned through this research by checking the boxes below:

I would like to be contacted if relevant information is learned about me/my family.

YES, contact me NO, DO NOT contact me INITIAL

I would you to contact my doctor if relevant information is learned about me/my family.

YES, contact my doctor NO, DO NOT contact my doctor INITIAL

If you wish that your doctor is notified of any potential results of the research tests, please give the name of your local physician and his/her address at the bottom of this form. Any available results will be forwarded and you can discuss with your physician the need, if any, for treatment.

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. There are no known risks from ultrasound tests.

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?

It is possible that we learn something about your personal and/or family history of kidney disease. However, it is unlikely that you or your family will benefit directly from this study. We

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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

If you do not wish to participate in this study, you may nonetheless wish, as a member of a family with an inherited disturbance of kidney function, to have your kidney function determined to ascertain whether or not you have this condition. You may choose to have this test even if you decide not to participate in this research study.

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 other treatments or procedures are available for my condition?

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.

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What should I do if I want to stop taking part in the 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, if needed.

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.

Will I be paid to take part in this research study?

There is no compensation for taking part in this research study at this time.

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 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.

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If I have questions or concerns about this research study, whom 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 M-F 9-5. You can also call the genetic counselor and research coordinator, Andrea Uscinski Knob, MS, at 617-525-5885 M-F 9-5 or email her at auscinski@rics.bwh.harvard.edu anytime with questions about this research study.

If you have questions about the scheduling of appointments or study visits, please contact Andrea Uscinski Knob, MS at 617-525-5885 or auscinski@rics.bwh.harvard.edu

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?

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.

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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. This may include information about hospital admissions or visits during this study, so that we know about any possible problems or side effects. 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 information that could mean harm to you or others, we may need to report this to a public health or public safety authority, or to specific individuals as required by law
- For treatment, payment, or health care operations

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

1. People or groups within Partners

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- 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.
- **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

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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.

Informed Consent and Authorization

Statement of Study Doctor or Person Obtaining Consent

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

Study Doctor or Person Obtaining Consent

Date/Time

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.

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- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.

Signature of Subject:

I give my consent to take part in this research study and agree to allow my health information to be used and shared as described above.

Subject Date/Time

Signature of Parent(s)/Guardian for Child:

I give my consent for my child to take part in this research study and agree to allow his/her health information to be used and shared as described above.

Parent(s)/Guardian for Child Date/Time

Signature of Guardian or Authorized Representative for Adult:

I give my consent for the person I am authorized to represent to take part in this research study and agree to allow his/her health information to be used and shared as described above.

Print Name (check applicable box below)

- Court-appointed Guardian
- Health Care Proxy
- Durable Power of Attorney

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Family Member/Next-of-Kin

Signature Date/Time

Relationship to Subject: _____

Assent

Statement of Person Giving Assent

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

Signature of Child:

I agree to take part in this research study and agree to allow my health information to be used and shared as described above.

Child, Ages 14-17 Date/Time

Signature of Adult with Impaired Decision-making Capacity:

I agree to take part in this research study and agree to allow my health information to be used and shared as described above.

Adult with Impaired Decision-Making Capacity Date/Time

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Witness to Consent of Non-English Speaking Subjects Using the “Short Form” in the Subject’s Spoken Language

Statement of Witness

As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject’s own language, and that the subject was given the opportunity to ask questions.

Witness _____
Date/Time

Witness to Consent of Subjects Who Cannot Read or Write

Statement of Witness

I represent that the consent form was presented orally to the subject in the subject’s own language, that the subject was given the opportunity to ask questions, and that the subject has indicated his/her consent and authorization for participation by (check one box as applicable):

- Making his/her mark above
- Other means _____
(fill in above)

Witness _____
Date/Time

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