

Partners HealthCare System Research Consent Form

Subject Identification

Certificate of Confidentiality Template
Version Date: April 2010

Protocol Title: The MedSeq™ Project Pilot Study: Integrating Whole Genome Sequencing into Clinical Medicine

Principal Investigator: Robert C. Green, MD, MPH

Site Principal Investigator:

Description of Subject Population: Healthy adults in Primary Care

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.

Partners HealthCare System is made up of Partners hospitals, health care providers, and researchers. In the rest of this consent form, we refer to the Partners system simply as “Partners.”

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.

Why is this research study being done?

This research study is being done to explore how patients and their physicians understand and use information about a patient’s whole genome in healthcare decisions. DNA is found inside your cells and contains the instructions needed to direct how your body grows, develops, and functions. Individual segments of DNA are called genes. All of the DNA in a single cell of the body (the entire set of instructions) is called the genome. Much of the genome is similar between people, but there are some differences. Some of these differences cause differences in appearance (like hair and eye color) and others contribute to certain diseases or health conditions. Recently, scientists have developed technology to sequence the DNA, called whole genome sequencing. This means that scientists can “decode” most of the genes in your DNA. Right now, whole genome sequencing is not done very often because it is expensive and we don’t always know how to use all of the information. It is important that scientists and the medical community understand the thoughts, feelings, and attitudes of patients and their

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physicians toward whole-genome sequencing, and how they understand and use the information gained from sequencing the genome in healthcare.

We are asking you to take part in this study because you are a generally healthy adult and you see a Primary Care Physician at Partners. Your Primary Care Physicians is also taking part in this study. Your Primary Care Physician has been asked to recruit his or her patients and will answer survey and interview questions as part of the study. Your physician will be compensated for participating in this research study.

Approximately 200 subjects will take part in this study, all at Brigham and Women's Hospital (BWH). We expect to enroll approximately 10 Cardiologists (heart doctors) and 100 of their patients with a heart disease called cardiomyopathy and approximately 10 Primary Care Physicians and 100 of their generally healthy adult patients.

The National Institutes of Health is paying for this study to be done. This study is part of a genomic sequencing effort called the MedSeq Project.

How long will I take part in this research study?

It will take you about one year to complete this research study. During this time, we will ask you to make approximately 4 to 6 study visits.

What will happen in this research study?

If you choose to take part in this study, we will ask you to sign this consent form before we do any study procedures.

If you read this consent form and decide not to take part in this study, we will ask you some questions about why you decided not to take part. We want to better understand why people do or do not choose to take part in studies like this.

Baseline study visit (Visit 1)

This visit will take about 1-2 hours. At this visit, we will:

- Review the consent form with you, and answer any questions you have about participating.
 - We will ask for your permission to audio-record the conversation about the consent form, so that we can better understand the questions and concerns participants have about our study. We will not include any of your identifying information on the recording. The audio recording of this interview will be

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labeled and analyzed using your study number and not your name or other identifying information, and it will be shared with the MedSeq Project investigators at Baylor College of Medicine, Duke University and University of California San Francisco. If you do not want the conversation to be recorded, it will not affect your participation in the study. If you decide not to enroll in the study, the recording will be erased.

- Have you fill out a survey with questions about
 - your demographic information (age, race, gender, job, etc)
 - your thoughts about learning about your genetic information
 - your thoughts about how likely you are to develop certain diseases
 - your current health and health habits
 - your health insurance coverage
 - current symptoms of anxiety and depression. (After your study visit, we will look at your responses to these questions. If we have any concern about your responses, the study doctor and the genetic counselor will be alerted and they will call you to discuss their concerns with you.)
 - any prescription medication you are taking (we will check your medical records to confirm information about what medications you are taking)
- Have you use an online program to fill out your family medical history
- Draw blood for possible genome sequencing. During the entire course of this research study, we will draw about 1-2 tablespoons of blood.

At this visit, we may ask you to complete an additional short interview along with our collaborators at University of California San Francisco and the University of Calgary. This interview is to help us develop a later survey that we will invite you to complete after you learn your results, which is designed to assess how individuals make the decision to pursue whole genome sequencing. This interview will be audio-recorded, and our collaborators at University of Calgary and a research company who is helping to design this interview and a later survey, called RTI International, will listen in to the interview by phone and/or video conference. Your responses will be analyzed using your study ID number and not your name or any other identifying information, and will be shared with these investigators. Participation in this additional short interview is completely voluntary and you may decline to participate without affecting other aspects of your participation in this study.

After the first study visit, the study staff will assign you by chance (like a coin toss) to either receive or not receive whole genome sequencing. Neither you or your doctor can choose your study group.

If you are assigned to the group that will receive whole genome sequencing, the study staff will send your blood to the Partners Laboratory for Molecular Medicine (LMM). The study staff at

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the LMM will send one tube of your blood to a clinical laboratory called Illumina, Inc. to conduct the whole genome sequencing. Another tube of your blood will be sent to the Brigham and Women’s Hospital Blood Bank to test your blood type. The LMM will store one tube of your blood in case any laboratory tests are needed to confirm certain genome results before reporting them to you and your physician. Since the laboratories at Illumina, Inc., the BWH Blood Bank and the LMM are clinical laboratories, your blood samples will be labeled and analyzed with your name, gender, and date of birth. These personal pieces of information are important for the laboratories to have in order to ensure that your sample is not confused with someone else’s sample.

If you are randomly assigned to the group that will NOT receive whole genome sequencing, your blood samples will be safely thrown away. We decided to randomly assign subjects in this study to either receive whole genome sequencing or NOT receive whole genome sequencing in order to best study how information from the genome is understood and used in healthcare. This is a similar approach to studies of new drugs, in which one group of subjects receives the medication and the other group receives a placebo.

You will not learn which group you were randomly assigned to until you come back for the third study visit.

We recognize if you are assigned to the group that does NOT receive whole genome sequencing you may be disappointed to learn this and may still wish to receive this information. Therefore we will offer whole genome sequencing to three randomly chosen participants from the group that has NOT received whole genome sequencing as part of the research study. At the third study visit if you NOT received whole genome sequencing you will have the opportunity to enter a lottery to receive whole genome sequencing. Participation in the lottery is completely voluntary. The lottery will be drawn at three even intervals throughout the study (after an equal number of participants have completed visit three). If you elect to participate in the lottery you will have approximately a 1 in 33 chance of receiving whole genome sequencing. If you elect to participate in the lottery, you will learn if you have won the opportunity to receive whole genome sequencing at your six-month follow up visit (visit 5). Results will be reported to the lottery winners by their physicians or the study physician Dr. Robert Green. We will not ask you to complete additional surveys or interviews after receiving whole genome sequencing through the lottery, but we will share your genome sequencing data and include you in the medical record review as outlined later in this consent form. Results of the whole genome report will not be put in your medical record. However, it will be at the discretion of your physician to document in your medical record information learned through whole genome sequencing that may impact your health.

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In-person interview (Visit 2)

The study staff may contact you to set up a time to come in to the research clinic again for an in-person interview with the study staff. This interview will last about an hour. The purpose of this interview is to collect additional information about your attitudes, thoughts, and feelings about learning information from your genome. This additional interview will be taped (audio only). The audio recording of this interview will be labeled and analyzed using your study number and not your name or other identifying information, and it will be shared with the MedSeq Project investigators at Baylor College of Medicine, Duke University and University of California San Francisco.

Approximately 3 to 6 months after having your blood drawn, your doctor will receive your reports.

If you are randomly assigned to the group that will receive the results of your whole genome sequencing, your doctor will receive a report that includes information from your whole genome sequence and your family history.

If you are randomly assigned to the group that will NOT receive the results of your whole genome sequencing, your doctor will receive your family history information only.

Once your doctor receives the report(s), he or she will take some time to review and understand the report(s). Your doctor may consult with the study staff in order to make sure he or she understands the information included in your report(s) before discussing the report(s) with you. Once your doctor is prepared to discuss your report(s) with you, the study staff will call you and schedule a time to meet with your doctor and discuss your results.

If you decide that you would like to withdraw from the study before learning your results, we will destroy your report.

Learning your results (Visit 3)

This visit will take 1 hour to 2 ½ hours. At this visit:

- You will have an in-person meeting with your doctor to discuss your report(s)
- You will fill out a survey about your thoughts and understanding of the information in your genome report
- Separate from you, your doctor will fill out a survey about what medical decisions, if any, he or she is considering about your healthcare as a result of learning the information included in your report.

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Your genome report and/or family history may contain information about:

- Your risk of developing certain diseases, such as cancer or heart disease, for which preventative measures or screening may help reduce the risk of getting the disease.
- Your risk of developing certain diseases or conditions, such as having an arrhythmia (an irregular heart beat), for which there are no preventative measures to reduce your risk, but there are treatments available.
- Your risk of developing certain diseases, such as Amyotrophic lateral sclerosis (ALS) (a progressive neurological disease that affects the muscles), for which there are no preventative measures to reduce your risk and no cures or treatments available.
- Genetic disorders that could affect you or members of your family.
- Genetic changes that influence the onset and/or treatment of heart disease.
- How your body breaks down and reacts to certain medications. This information might be useful if you need to take one of these medications.
- Your blood type

Some of the information in your genome report will be things that have been found in other people and studied by scientists and doctors. There may be other information in your genome report that we do not understand yet. The genome report will NOT include your entire DNA sequence. Your genome report will only include information about you that potentially could be relevant to your healthcare; therefore it will not include other information about personal genetic traits such as eye or hair color.

We may use information from your genome sequence that tells us about your ancestry in order to best interpret certain results. The reason is that our scientific knowledge about how certain findings impact your risk of disease is sometimes dependent on your ancestry, or where your relatives came from thousands of years ago. Information about your genetic ancestry may or may not be included in your report, depending on whether it is needed to interpret a particular finding on your Genome Report. It is important for you to know that your genetic ancestry may be different than how you describe yourself in terms of your race or your ethnicity.

When you meet with your doctor to review your results, your doctor will audio-record the conversation. The audio recording will be sent to the MedSeq Project investigators at Baylor College of Medicine, Duke University and University of California San Francisco who are interested in analyzing topics of conversations between doctors and their patients. The audio recording will be labeled with your unique study ID number and not your name or any other identifying information.

All of your reports will be placed in your medical record.

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If you decide to withdraw from the study after your report(s) are placed in your medical record, then your report(s) will remain in your medical record (they cannot be removed).

Six-week follow-up visit (Visit 4)

Approximately six weeks after learning your results from your doctor, the study staff will contact you to set up a time to come back to the research clinic for an in-person follow-up visit. This visit will last about 30 minutes. At this visit, you will fill out a follow-up survey to which will ask about your attitudes, thoughts, and feelings toward learning your genome and/or family's medical history information, as well as look for symptoms of anxiety and depression. After your study visit, the study staff will look at your responses to these questions. If the study staff have any concern about your responses, the study doctor and the genetic counselor will be alerted and they will call you to discuss their concerns with you.

Six-month follow-up visit (Visit 5)

The study staff will contact you again at approximately six months after learning your results. This visit will be similar to Visit 4.

In-person interview (Visit 6)

This is the last study visit. It will take about an hour to complete. After your six month follow-up visit, the study staff may contact you to set up a time to come in to the research clinic for another in-person interview with the study staff. The purpose of this interview is to collect additional information about your attitudes, thoughts, and feelings about learning about your genome and/or family's medical history information. This interview will be recorded, and the audio recording of this interview will be labeled and analyzed with your study number and not your name or other identifying information. The recording will be shared with the MedSeq Project investigators at Baylor College of Medicine, Duke University and University of California San Francisco.

Use of Your Study Information

After all the subjects in this study have learned the results of the genomic testing, the study staff will conduct a review of the medical records of all the subjects who have completed this study. This will be done through a computerized system called the Partners Research Patient Data Registry (RPDR). We are doing this to learn about whether genome information affects things like the average number of office visits per year for patients or the number of medical imaging tests ordered by physicians. The study staff may also review other aspects of your medical record, such as notes written by your doctor. The data gathered from your medical record review will not be analyzed on an individual basis but rather as a whole with data from all study

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participants. All audio recordings taken as part of this study will be kept for 10 years after the completion of the study.

At the end of this study, if you were in the group that received whole genome sequencing, your full genome sequencing data will be stored at the Partners Laboratory for Molecular Medicine (LMM) for the duration of the study funding or for at least two years after your genome is sequenced. A shortened version of your genome sequencing data and all your reports will be stored at the LMM indefinitely (for an unknown amount of time). Your reports will also be stored at the BWH Adult Genetics Clinic/Personal Genomic Consultation Service, and the doctors there will notify your doctor if the LMM updates your Genome Report.

If you were assigned to the group that did NOT receive whole genome sequencing and you are interested in obtaining your whole genome sequencing information, you may ask the study staff to direct you to any other research studies, clinical, or commercial services that offer whole genome sequencing that are available at that time. The study staff will direct you to all options, some of which may require you to pay out-of-pocket in order to obtain your whole genome sequencing information.

Storage and sharing of the whole genome sequencing data

Your whole genome sequence, or specific information from your sequence, may be shared with other researchers within and outside Partners in order to advance science and medical care. If you are also enrolled in the Partners HealthCare Biobank (Partners Biobank), your genome sequence will be shared with the Partners Biobank.

The National Institutes of Health (NIH) maintains databases containing research study data. Some of these databases are accessible by the Internet. Information from analyses of your genome sequence and your medical history may be put in these databases along with information from the other subjects from this and other research studies. There are two levels of access to these databases:

- 1) Open-access, in which select information (such as information about the questions we ask in our surveys and large trends or findings from this study) is available to anyone who visits the database website. None of your personal information will be available by open-access.
- 2) Controlled-access, in which only researchers who are federally funded and affiliated with an NIH institute or center, or have received approval from a NIH Health Data Access Committee, can access data. Your coded genome sequence, medical information, and family history report may be put in the controlled-access database and viewed only by those researchers who have permission. The controlled-access

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database is password protected. The information available on these databases will be de-identified, meaning personal information such as your name and date of birth will be removed. Only the MedSeq Project study staff will have access to the code that links your data to your personally identifying information.

Future Contact

The MedSeq staff may contact you in the future by phone call or letter regarding future research opportunities. Participation in future research is completely voluntary. Your decision to participate in any research, present or future, will not impact your medical care at Partners.

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

Risks and discomfort resulting from whole genome sequencing

- It is possible that an insurance company may ask to look at at your genome test results before making a decision about life, disability, or long-term care insurance. Since the reporting of genome testing results in your medical record, as will occur with this study, has not been done before, the behavior of insurance companies as it relates to this information is unclear. The Genetic Information Non-Discrimination Act of 2008 (GINA) is a federal law that provides additional protection against genetic discrimination, specifically in the areas of employment and health insurance coverage. It does not specifically cover long-term care insurance, life insurance and disability insurance. Despite GINA and the legal protections it offers, the results generated in this research could effect your future insurance eligibility or insurance premiums. Before enrolling in this study you may wish to review your current insurance coverage and explore life, long-term care and disability insurance options.
- Added medical costs - If you or your doctor seeks additional medical tests to follow up on genetic risks revealed in the results, you may be responsible for these costs.
- Emotional or psychological distress from learning genetic information about yourself or your family members.
- Emotional or psychological distress from learning unexpected and possibly upsetting information about yourself or your family members, such as that you may have a different parental or ethnic background than you thought.
- Loss of privacy. While the databases that will store the genome sequencing information will not contain information that is traditionally used to identify you (such as your name, address, telephone number, or social security number), in the future, people may develop ways to allow someone to link your genetic or medical information in these databases back to you. For example, someone could compare information in our databases with information from you (or a blood relative) in another database and be able to identify you

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(or your blood relative). It also is possible that there could be violations to the security of the computer systems used to store the codes linking your genetic and medical information to you. We think this is very unlikely, though.

Since we are still learning about the human genome and what certain changes found in the human genome mean for an individual's health and wellness, we may find changes in your genome but not know with certainty what it means for your health. Additionally, we may learn information about whether you might get a disease in the future for which there are no preventative measures, treatments, or cures. This could be surprising, frustrating, upsetting, or emotionally distressing.

We plan to only return results to you if we feel that there is strong evidence that they may help you manage risk of disease, predict future disease, tell you that you carry a recessive gene that could impact a future child or help predict your response to a drug. Despite that, we may give you information that we later find out was not reliable (not predictive). If that happens, you may have been be unnecessarily upset.

Since the availability of information about a person's whole genome is new, there may be other risks that are currently unknown. Currently, we believe that the risks to you and your family as a result of participating in this study are low, and we believe that the benefits of learning more about how to integrate whole genome sequencing in healthcare outweighs these potential risks. The study investigators, the MedSeq Project Monitoring Committee will monitor these risks. We will let you know if there is any new information about the risks of taking part in this study.

Risks and discomfort from the blood draw

You may have a bruise (a black-and-blue mark) or pain where we take the blood samples. There is also a small risk of feeling lightheaded, fainting, or infection.

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

Benefits to you

You may not benefit from taking part in this research study. You may not benefit from learning information from your whole genome or in learning about your family's medical history.

However, information discovered by sequencing your genome or looking more deeply at your family's medical history may provide you and your doctor with information about your risk of developing diseases, and how your body might react to certain medications.

Benefits to society

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We hope that what we learn from the MedSeq Project will provide society with important new knowledge about how information about a person's whole genome may be useful or harmful within the current healthcare system.

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.

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?

If you complete all of the study visits and the surveys included at those visits, you will receive \$125.00. There are four in-person study visits and four in-person surveys total. You will not receive payment if you do not complete all four surveys.

In addition to these four study visits and four surveys, if you are asked to participate in the additional in-person interviews and you complete those interviews, you will receive \$40 for each interview that you complete. If you complete all the study visits, surveys, and in-person interviews, you will receive \$205 for taking part in this study.

The cost of valet parking to attend your study visits will be paid for by the research study.

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

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Study funds will pay for the cost of the blood draw, sequencing and interpreting your genome, reviewing your family history, and meeting with your doctor to discuss the results. You or your health insurer will be responsible for the costs of any additional doctor's visits (even if they are related to information about your genome and/or your family history), and any healthcare costs for tests or visits to follow up on information learned from the genomic sequencing in this study.

You will be responsible for payment of any deductibles and co-payments required by your insurer for this routine care or other billed care by your doctor. If you have any questions about costs to you that may result from taking part in the research, please speak with the study doctors and study staff. If necessary, we will arrange for you to speak with someone in Patient Financial Services about these costs.

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. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. 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, 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.

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Robert C. Green, MD, MPH is the person in charge of this research study. You can call him at (617) 264 – 5834 Monday – Friday 9:00 AM – 5:00 PM. You can also call Denise Lautenbach, MS at (617) 264 – 5837 Monday - Friday 9:00 AM – 5:00 PM with questions about this research study.

If you have questions about the scheduling of appointments or study visits, call Rachel Miller at (617) 264-5885 or Denise Lautenbach, MS at (617) 264 – 5837 Monday - Friday 9:00 AM – 5:00 PM.

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 to protect the privacy of health information that identifies you. In the rest of this section, we refer to this information simply as “health information.”

In this study, we may collect health information about you from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Certificate of Confidentiality for Health Information and Other Identifying Information from the Research

In this research study, we have obtained a Certificate of Confidentiality from the Department of Health and Human Services (DHHS). By granting the Certificate, DHHS is not approving the research itself, but is helping us strengthen the privacy protections for your health information and other identifying information from the research. With the Certificate, we cannot be forced (for example by court order or subpoena) to disclose your health information or other identifying information from the research in any Federal, State or local civil, criminal, administrative,

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legislative, or other proceedings. (Note that information that is not from the research, such as existing hospital or office health records, is protected by general privacy law but does not receive the Certificate's stronger protection. The Certificate also does not prevent you or a member of your family from voluntarily releasing any information about yourself or your involvement in this research study.)

Why Health Information and Other Identifying Information from the Research Might Be Used or Shared, and By/With Whom

Even with these privacy protections, your health information and other identifying information from the research may still be used within Partners by the researchers and the staff involved in this research study, by the Partners ethics board that oversees the research, and by other staff within Partners who need the information to do their jobs (such as for treatment, payment (billing) or health care operations such as overseeing the quality of care or research). Your information may also be shared by these groups with others outside of Partners for certain purposes as follows.

We may use and share your information with:

- 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 and their ethics boards
- A group that oversees the data (study information) and safety of this research
- People or groups that we hire to do certain work for us, such as data storage companies, insurers, and lawyers
- Federal and state agencies (such as DHHS and agencies within DHHS like the Food and Drug Administration, the National Institutes of Health, and the Office for Human Research Protections), with other U.S. or foreign government bodies, and with organizations that provide independent accreditation and oversight of hospitals and research. For example, disclosure may be necessary upon request of DHHS for an audit, program evaluation, or investigation. Disclosure may also be necessary if required by the federal Food, Drug, and Cosmetic Act or its regulations.
- A public health or public safety authority, or with specific individuals who may be at risk of harm, if we learn information that could mean harm to you or others. When state mandatory reporting statutes would require us to disclose information, including about child or elder abuse, we will voluntarily disclose that information.

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As described above, we have obtained a Certificate of Confidentiality for this research study. With the Certificate, we cannot be forced (for example by court order or subpoena) to disclose identifying information from the research. However, certain information from the research that relates to your general medical care will be included in your regular medical record by your doctor. For example, your doctor will include information about **information from your genome and/or your family's medical history in your medical record**. Any information from this research study that is placed in your medical record may not be protected by the Certificate. This information may be accessible by court order or subpoena, or by your health insurer, by your doctors or hospitals, or by others for treatment, payment, health care operations or other purposes. Please ask us if you have any questions about what information will be included in your medical record.

Some people or groups outside Partners who get your health information or other identifying information from the research might not have to follow the same privacy rules that we follow. We share your 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.

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. The protections of the Certificate of Confidentiality and other Partners privacy protections will continue to apply to your health information and other identifying information from the research for as long as our researchers keep the information.

The results of this research 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.

Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your health information for research; however, if you don't sign it, you can't take 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. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. The Certificate of Confidentiality and other Partners privacy

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protections will continue to apply to your health information and other identifying information from the research that our researchers keep.

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. You may only get such information after the research is finished.

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.
- 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

Consent Form Version Date: March 3, 2014