Partners HealthCare System
Research Consent Form

Subject Identification

General Template
Version Date: February 2010

Protocol Title: Randomized clinical trial of Vitamin D and Omega-3 Fatty Acids for Diabetic Kidney Disease (VITAL Diabetes)

Principal Investigator: Debra Schaumberg, ScD, OD, MPH

Site Principal Investigator:

Description of Subject Population: Participants in the main Vitamin D and Omega-3 Trial (VITAL) who have been diagnosed with diabetes.

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team is available to 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 the last page of this form (page 9) and return it along with your urine specimen to show you want to take part. Please keep the rest of this consent form (pages 1 thru 8) for your own records.

Why is this research study being done?

This research study is a "sub-study" of the Vitamin D and Omega-3 Trial (VITAL). The sub-study is called "VITAL Diabetes." It is being done to determine whether the VITAL treatments (vitamin D and omega-3 fish oil) help prevent health problems that are important to people with diabetes. In particular, the VITAL Diabetes sub-study will assess effects of VITAL treatments on the kidneys. This sub-study will not involve taking any extra pills.

We are asking you to take part in the VITAL Diabetes sub-study because you indicated on a VITAL questionnaire that you had been diagnosed with diabetes. About 1,500 people with diabetes who are participating in the main VITAL trial will also take part in the VITAL Diabetes sub-study. The National Institutes of Health is paying for the study to be done. For the sub-study, we are working closely with investigators at the University of Washington, led by Ian de Boer, MD.

How long will I take part in this research study?

The VITAL Diabetes sub-study lasts 4 years. When you finish the VITAL Diabetes sub-study, you will continue participating in the main VITAL trial. It is possible that the VITAL Diabetes sub-study might be extended. If this happens, we will ask you whether you want to participate longer, and this will be optional.

What will happen in this research study?

The VITAL Diabetes sub-study involves questionnaires, urine collections, and a blood collection. All of these activities can be done by mail. In more detail, the sub-study activities are:

- **Diabetes questionnaire.** We will ask you to complete a diabetes-related questionnaire two times, now and at the end of the study (in about 4 years). Questions will address your diagnosis of diabetes, health problems that you have had related to diabetes, problems with your kidneys, and medications related to diabetes. The questionnaire is 4 pages long and will take about 20 minutes. You don't have to answer all of the questions if you don't want to.
- **Urine sample.** We will ask you to collect a urine specimen twice, now and at the end of the study (in about 4 years). Each time, we will send you a urine collection kit that includes everything you need to collect the urine at your home and mail it to us. We will ask for about 2 teaspoons of urine. FedEx will pick up the urine and bring it to our laboratory. The first urine collection kit is included with this Consent Form.
- **Blood sample.** We will ask you to collect a blood sample at the end of the study (in about 4 years). We will provide you with a blood collection kit that includes all the materials needed to collect the blood and mail it to us. We will ask for about 2 tablespoons of blood. This can be drawn by a health care provider near your home. FedEx will pick up the blood and bring it to our laboratory.

- **Using blood and information collected for the main VITAL trial.** On a main VITAL trial questionnaire, you indicated that you would be or might be willing to provide a blood sample. This blood sample will be collected at the beginning of the main VITAL trial, and you may have provided it already. Working with the main VITAL trial researchers, we will use a small amount of blood from that sample for the VITAL Diabetes sub-study. This avoids any need to collect a separate blood sample for the VITAL Diabetes sub-study. We will also use information you provide to the main VITAL trial. For example, on questionnaires, you provide information about your age, gender, race, medical history, medication use, lifestyle patterns (like physical activity, smoking, and alcohol use), height, weight, and blood pressure. We will also use information about your use of study medications during the main VITAL trial, changes in your health during the main VITAL trial, and results of blood tests performed by main VITAL trial researchers. If you give consent to the main VITAL trial to use your DNA (but ***only*** if you give consent to use your DNA), we will also use information about your genetic makeup.
- **Repository.** Extra urine and blood from the samples you provide to the VITAL Diabetes sub-study will be added to the VITAL blood and urine repository ("bank"). This is the same repository used for main VITAL trial blood samples. Providing a main VITAL trial blood sample is a requirement to participate in the VITAL Diabetes sub-study.

  The collection, storage, and use of the main VITAL trial blood sample are described in detail in the blood sample consent form. The extra urine and blood collected for the VITAL Diabetes sub-study will be stored and used the same way as your main VITAL trial blood sample. This means that all of your samples will be labeled only with code numbers (not your name and other identifiers) and stored in freezers at Brigham Women's Hospital. The health information that you provide on questionnaires is stored in a separate computer database. Only the repository Principal Investigator and authorized study staff will have access to the database that links your sample and medical information to your name and other identifiers.

  Your samples will be made available for researchers at Brigham Women's Hospital, Massachusetts General Hospital, and other Partners institutions, as well as non-Partners academic institutions including the University of Washington and for profit companies that are working with Partners or University of Washington researchers on a specific research project. Researchers outside of Partners will not be given the key to the code that links your sample and medical information to your name and other identifiers.

Your samples and information may be used for research on a wide variety of conditions. There is no scheduled date on which your samples and information in the bank will be destroyed. Your samples may be stored for research until they are "used up." You have a right to ask to have your samples stop being used in research at any time. You will not get the results of research done with your extra samples. You may ask more questions about the repository at any time.

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

The blood draw may cause pain at the place where the needle is inserted, bruising, a hematoma (collection of blood underneath the skin), or infection at the place where the needle is inserted. Some people feel anxious with blood draws and may faint.

The main risk of allowing us to store and use your samples and certain limited health information for research is a potential loss of privacy. We will protect your privacy by labeling your samples and information only with a code, and keeping the key to the code in a password protected database.

Information that could be used to identify you will only be shared with researchers within Partners who have approval of the Partners ethics board. Information that likely could be used to identify you will not be shared with researchers outside Partners.

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

You will not directly benefit from taking part in this research study. If this research study shows that vitamin D or omega-3 fish oil helps prevent health problems for people with diabetes, this could improve the health of patients with diabetes in the future.

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.

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

Study funds will pay for all urine collection materials, blood collection materials, questionnaires, and mailing costs. If any study materials are lost or damaged, study funds will pay for new ones.

Will I be paid to take part?

We will not pay you to allow us to store your samples and to allow research on your samples. We may use your samples and information to develop a new product or medical test to be sold. The Sponsor, hospital, and researchers may benefit if this happens. There are no plans to pay you if your samples are used for this purpose.

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.

Debra Schaumberg, OD, and JoAnn Manson, MD, are the people in charge of this research study. You can call them at 1-877-517-2555, Monday-Friday 9-5.

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?

During this research, identifiable information about your health will be collected. In the rest of this section, we refer to this information simply as "health information." In general, under federal law, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use, and share your health information for research and why they may need to do so.

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

Who may see, use, and share your identifiable health information and why they may need to do so:

- Partners research staff involved in this study
- The sponsor(s) of this study, and the people or groups it hires to help perform this research
- Other researchers and medical centers that are part of this study and their ethics boards
- A group that oversees the data (study information) and safety of this research
- Non-research staff within Partners who need this information to do their jobs (such as for treatment, payment (billing), or health care operations)
- The Partners ethics board that oversees the research and the Partners research quality improvement programs.
- People from organizations that provide independent accreditation and oversight of hospitals and research
- People or groups that we hire to do work for us, such as data storage companies, insurers, and lawyers
- Federal and state agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health, and other US or foreign government bodies that oversee or review research)
- Public health and safety authorities (for example, if we learn information that could mean harm to you or others, we may need to report this, as required by law)
- 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.

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 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.

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.

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 Person Giving Informed Consent and Authorization

Please read, sign and date, and return this page with your questionnaire and urine kit

- I have read this 9-page consent form.
- I have been given the names and contact information of study team members that I can speak to in the event that I have questions or concerns about the research study.

I understand:

- the information given to me, including that this research study is a "sub-study" of the main VITAL trial, and that I can only participate in this sub-study if I also participate in the main VITAL trial and provide the main VITAL trial optional blood sample.
- that I will be asked to complete a diabetes questionnaire and collect a urine sample now, and that at the end of this sub-study (about 4 years from now), I will be asked to repeat the diabetes questionnaire, collect another urine sample, and collect a blood sample.
- that extra urine and blood from the samples I provide for this sub-study will be placed into the VITAL blood and urine repository ("bank"), where it is labeled with a code, not my name, but will remain linked to the other information I provide and my identity. My extra urine and blood may be used for research on a wide variety of conditions. They may be shared with researchers at other academic sites as well as for-profit companies.
- that there is no direct benefit to me and I will not need to pay or be paid to take part in this sub-study.
- that the risks are the risk of having a blood sample taken and a potential loss of privacy
- that I can keep pages 1-8 of this form and must return, along with my questionnaire and urine kit, only this page with my signature below in order to provide consent.

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: December 14, 2010