

	Human Research Protection Program Institutional Review Board Vitamin D and Type 2 Diabetes (D2d) study Permission for Storage of Biological Materials for Future Studies D2d Research Repository	
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STUDY TITLE: Vitamin D and type 2 diabetes (D2d Study)

CONSENT VERSION DATE: July 30, 2013

HOSPITAL OR INSTITUTION: Maine Medical Center

INVESTIGATOR: Irwin Brodsky, MD, MPH

SUBJECT'S NAME (printed): _____

INTRODUCTION

Research using tissues is an important way to try to understand human disease. You have been given this information because the investigators want to include your tissues (blood, urine, and DNA) in a research project and because they want to save the samples for future research. There are several things you should know before allowing your tissues to be studied.

You are being invited to take part in the D2d Research Repository, an expansion of the D2d study. A repository stores and distributes samples and data from people with many kinds of disorders and from healthy people. The purpose of this collection is to make samples collected during the D2d study, available for use in research for the study of vitamin D, nutrition, metabolism, diabetes and other health problems, after the D2d study is completed. Stored samples will give scientists valuable research material that can help them develop new diagnostic tests, new treatments or new ways to prevent diseases.

We are asking you to provide additional samples of your blood and urine, including blood for DNA. During the study, samples will be stored in the D2d Central Laboratory, which is in the Laboratory for Clinical Biochemistry Research (LCBR) at the University of Vermont. After the D2d study is completed, samples and data will be stored at the National Institute of Diabetes And Digestive And Kidney Diseases (NIDDK) Central Repositories. In this document, the term Repository refers to both the D2d Central Laboratory and NIDDK Central Repositories

Your tissues will be stored as follows:

The D2d researchers at Maine Medical Center would like to store blood and urine leftover from the samples you provided during the main D2d study visits and collect additional blood and blood for DNA (genetic material) for the Repository. Before the researchers at Maine Medical Center send samples to the Repository, they will assign your sample a code number. The code number will connect your sample to data collected during the D2d study such as age, gender, race, whether you received placebo or Vitamin D and study results. Your name and personal identifying information, such as address, date of birth, will not be included. Therefore, researchers that use your samples will not have access to your name or other information that could identify you.

The following table shows what additional samples will be collected for the Repository.

D2d Study Visit	Additional specimens to be collected for the Repository
Baseline (visit 2)	1½ tablespoons of blood 1 tablespoon of urine 1½ teaspoon of blood for DNA
Month 6 (visit 4)	1½ tablespoons of blood
Month 12 (visit 5) Month 24 (visit 7) Month 36 (visit 9) Month 48 (visit 11)	1½ tablespoons of blood 1 tablespoon of urine

USE OF SAMPLES

The long-term goals of the research that will be conducted using your stored samples are to better understand the effects of vitamin D and nutrition on health and metabolism, and how to prevent, diagnose or treat diabetes and other health conditions, including - but not limited to - heart, lung and blood diseases, neurological or brain diseases, arthritis and muscle-bone diseases, allergies and infectious diseases and cancer. It is not possible to list every research project your sample maybe used for in the future. This is why we ask permission to use your samples and data for future research that we cannot specify. As we learn more, new types of research, new research techniques and new research questions related to vitamin D, nutrition, metabolism, diabetes and associated health conditions may arise. Your donation of samples and data into this Repository may offer unique opportunities for future discoveries that will improve our understanding of health and disease.

The results of the study of your samples will be used for research purposes only and you will not be told the results of the tests.

TISSUE SAMPLING FOR GENETIC TESTING

We are also asking you to allow us to do genetic research on the DNA in your blood sample. DNA is the material that makes up your genes. All living things are made of cells. Genes are the part of cells that contain the instructions, which tell our bodies how to grow and work, and

determine physical characteristics such as hair and eye color. Genes are passed from parent to child. Genetic research will be done to help us understand the relationship between our genes, vitamin D, nutrition, metabolism, diabetes and other health conditions, including - but not limited to - heart, lung and blood diseases, neurological or brain diseases, arthritis and muscle-bone diseases, allergies and infectious diseases and cancer.

In genetic studies, researchers usually study just a few areas of your genetic code that are linked to a specific disease or condition. We may also perform a whole genome research analyses on your DNA sample. In these studies, all or most of your genes are analyzed and used by researchers to study links to diseases.

Your samples may be made available to qualified scientists and researchers from hospitals and research institutions. The Repository will provide to researchers the samples and data collected during the D2d study. The samples and data will not identify you in any way. Any future researcher who conducts research on your stored samples will not be able to contact you. A possible risk of not knowing includes being unaware of the need for treatment. These risks can change depending on the results of the research and whether there is a treatment or cure for a particular disease.

After completion of the D2d study, your samples and data will be stored at the NIDDK Central Repositories. Your identity will be protected by the NIDDK Central Repositories in the same manner as during the D2d study. The NIDDK Central Repositories will release samples and data to qualified scientists for the purpose of conducting scientifically approved research.

Sometimes patients have been required to furnish information from genetic testing for health insurance, life insurance, and/or a job. A Federal law, the Genetic Information Nondiscrimination Act of 2008 (GINA), generally makes it illegal for health insurance companies, group health plans, and employers with 15 or more employees to discriminate against you based on your genetic information.

The results of the study of your samples from this project will be used for research purposes only, and you will not be told the results of the tests.

WITHDRAWAL FROM THE REPOSITORY

The samples will stay in the Repository indefinitely. If you agree to have your samples stored in the Repository, you can change your mind up until the end of the D2d study (when all participants have had the last study visit). If you decide to withdraw your samples, you should contact Dr. Irwin Brodsky by telephone at (207) 662-2208 or in writing to Dr. Irwin Brodsky, M.D., MPH, Clinical Outcomes Research And Evaluation, 509 Forest Avenue, Portland ME 04101-1512 and clearly inform him of your wishes. When the D2d study researchers receive instructions from you, they will destroy your samples. It will not be possible to withdraw samples after the Dd2 study has ended, or if the samples have been sent to outside researchers because they will not know which one is yours.

RISKS

The potential risk associated with allowing us to store and use your samples and certain limited health information for research is a potential loss of privacy. However, this risk is extremely low because **researchers will send the samples to the Repository with a code number. Your name and all personal identifying information, such as address and date of birth will be removed.** Results of genetic tests, if disclosed by mistake, could negatively affect access to insurance or employment or could have an impact upon family or social relationships. The researchers that will be conducting the genetic tests will ensure that the likelihood for unintended disclosure of genetic information to occur is minimal. As outlined above, extensive protections are in place to minimize this risk.

BENEFITS

You will not receive any direct benefit or payment for participating in the Repository, but your samples may benefit the future health of the community at large or a particular patient group. Because researchers using the stored samples will not have access to your identity, neither you nor your doctor will get the eventual results of studies that will be performed using your sample.

ALTERNATIVES

The choice to take part in this study is yours. You may choose to: (1) only donate blood and urine, (2) donate blood, urine and DNA or (3) not participate in this Repository by donating no samples.

PAYMENT

Any tissues you have donated which are used in research may result in new products, tests or discoveries. In some instances, these may have potential commercial value and may be developed and owned by the Investigators, MMC and/or others. However, donors of tissues do not retain any property rights to the materials. Therefore, you would not share in any financial benefits from these products, tests or discoveries.

☐ I consent to my samples being saved for future research

☐ I do not consent to my samples being saved for future research

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or a research-related injury contact Dr. Irwin Brodsky at 662-2208.

For questions about your rights as a research participant, contact the Maine Medical Center Institutional Review Board (which is a group of people who review the research to protect your rights) at (207) 396-8183.

MAKING YOUR CHOICE

Please read the question below and think about your choice. After reading each question, circle "YES" or "NO." If you have questions, please talk to the Principal Investigator and/or his representative.

I agree to the storage of my blood and urine samples for future research.

YES NO Participant's Initials _____

I agree to the storage of my blood for future DNA (genetic) research.

YES NO Participant's Initials _____

I have read, or have had read to me, the above information before signing this consent form. I agree to take part in this research study. I also give permission to use or share my personal health information for the purpose of this research. I have had the chance to ask questions. I have received answers that fully satisfy those questions.

Signature of Subject or Authorized Representative

Date 24 hour time

Printed Name of Subject or Authorized Representative

Relationship to subject (if applicable)

Person Obtaining Consent (required section for all studies)

Study representative statement

I have fully explained in terms understandable to the subject all of the following: the purpose of this research, the study procedures, the possible risks and discomforts and the possible benefits. I have answered all of the subjects and his/her authorized representative(s) question to the best of my ability. I will inform the subject of any changes in the procedure or the risks and benefits if any should occur during or after the course of the study.

Signature of the Person Obtaining Consent

Date 24 hour time

Printed Name of the Person Obtaining Consent

A signed copy of this consent form must be given to each subject entering the study.