D2d Protocol Appendix B
Vitamin D and Type 2 Diabetes (D2d) study
Informed Consent for Storage of Biological Materials for Future Studies
D2d Research Repository

Collaborating Clinical Site Principal Investigator: *[insert name]*
Collaborating Clinical Site Co-Investigators: *[insert names]*
Collaborating Clinical Site Study Telephone Number: *[insert telephone number]*

INTRODUCTION

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

Taking part in the Repository is entirely your choice. If you decide not to participate or - at any time and for any reason - change your mind after you agree to participate, your decision will not affect your care or treatment outside the D2d study, payment for your health care or health care benefits and you may still participate in the D2d study without participating in the Repository

If you decide to take part in this Repository, you will be asked to sign this form. You will be given a copy of the signed form. You should keep your copy for your records. The form has information, including important names and phone numbers, to which you may wish to refer in the future.

Please read all the information in this form carefully. Please ask the Principal Investigator, study doctor, or (*his/her*) representative, to explain any words, terms or sections that are unclear to you. You should also ask any other questions that you have about the Repository. Do not sign this consent form unless you understand the information in it and have had your questions answered to your satisfaction.

As a participant in the D2d study and the Repository, your identity, medical records, and data relating to this research will be kept confidential, except as required by law. Representatives from the U.S. Food and Drug Administration, which regulates investigational drug and device studies, National Institutes of Health (the study sponsor), the D2d study Coordinating Center) and representatives from Tufts Medical Center may look at records that identify you.

If you have questions about your rights as a research study participant, please call the *(insert official name of site IRB)* Institutional Review Board (IRB) at ###-###-#### *(insert IRB's telephone number).* The IRB is a group of researchers, doctors, nurses, and non-medical people who review human research studies for safety and protection of people who take part in the studies. Federal law requires the IRB to review and approve any research studies involving humans. This must be done before the study can begin. The study is also reviewed frequently while it is in progress.

The main D2d study and the present Repository have been reviewed and approved by the *(insert official name of site IRB)* IRB.

PURPOSE OF THE REPOSITORY

The purpose of the Repository is to collect and process additional samples during the D2d study and store them in a research specimen bank, until researchers need them to do additional research on 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. Repositories collect and store many types of samples, such as blood, urine or other materials from the body. Repositories have rules about which researchers can get samples and what kind of research they can do using the samples. The NIDDK, which is a branch of the National Institutes of Health, is sponsoring the D2d study and Repository.

SAMPLES COLLECTED AND STORED

During the D2d study, you will have blood and urine collected as part of the main study. The D2d researchers at *(insert name of D2d collaborating clinical site institution)* 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 *(insert name of D2d collaborating clinical site institution)* 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 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.

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.

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.

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 by telephone or in writing the *(insert name and contact information for site principal investigator or representative; please include telephone number as well as physical address)*, and clearly inform *(him/her)* 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.

WHOM TO CONTACT

If you have any problems or questions about the Repository, you may call one of the following members of the research team:

(Insert Site Principal investigator's name)	Phone Number	*###-###-####*
(Insert Site Research Coordinator name)	Phone Number	*###-###-####*

RESEARCH RELATED INJURY

Emergency medical treatment will be given to you if you are hurt or get sick as a direct result of taking part in this research study. Any needed medical care is available at the usual cost. All needed facilities, emergency treatment, and professional services are available to you, just as they are to the general public. You or your medical insurance company will pay for any such medical care. There are no plans to pay for your treatment if you get hurt or sick as part of this study. The institution where this research is being conducted has not set aside any money to pay for a research-related injury or illness.

COSTS

There is no cost to you to donate your samples to the Repository.

PAYMENT

You will not be paid to allow us to collect and store additional samples for the Repository.

Sometimes, research will result in findings or inventions that have value if they are made or sold. These findings or inventions may be patented or licensed, which could give an individual or a company the sole right to make and sell products or offer testing based on the discovery. Some of the profits from this may be paid back to the researchers and the organizations doing this study, but you will not receive any financial benefits.

PRIVACY AND CONFIDENTIALITY

The D2d study researchers and staff at the Repository will take measures to protect your privacy, although no guarantee of confidentiality can be absolute. Before the researchers send the samples to the Repository, each sample will be given a code number. Your name and all personal identifying information, such as address and date of birth will be removed. Therefore, the Repository will not be able to give out your name or other information that identifies you to the researchers who receive the samples. However, the Repository and scientist will have some information about you, for example, age, gender, race, medical history and the results of the D2d study.

It is possible that data resulting from use of your sample may eventually be used in a research publication. In that event, your name or other identifying information will not be included, as this information will not be available to the researchers.

A description of this study will be available on www.clinicaltrials.gov, as required by U.S. law. This web site will not include information that can identify you. At most, the web site will include a summary of the results for all participants. You can search this web site at any time.

MAKING YOUR CHOICE

Please read each 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_____

DOCUMENTATION OF CONSENT TO PARTICIPATE IN THE D2D RESEARCH REPOSITORY

I have been given a copy of this form. I have read it or it has been read to me. I understand the information and have had my questions answered to my satisfaction. I agree to participate in the D2d Research Repository, as noted below.

I understand that I will be informed of any new findings developed during the course of the main research study that may affect my willingness to participate in the D2d Research Repository.

_____ _____

Date Participant's Signature

I have fully explained to *[insert name of participant]* _____ the nature and purpose of the above-described study and the risks that are involved in its performance. I have answered all questions to the best of my ability.

_____ _____

Date Principal Investigator or Representative's Signature