Background

You are being invited to take part in the D2d Research Repository, an expansion of the D2d study. You cannot participate in this D2d Research Repository study unless you have provided consent to participate in the D2d study. A repository collects, stores and distributes many types of samples, such as blood, urine, or other materials from the body, and data from people with many kinds of disorders and from healthy people. 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.

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

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 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.

The Baylor College of Medicine Institutional Review Board (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 study involving humans. This must be done before the study can begin.

The study is also reviewed frequently while it is in progress. This research study has been reviewed and approved by the Baylor College of Medicine IRB. Also, an external monitoring committee is watching the study for information on safety.

Purpose

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.

Procedures

The research will be conducted at the following location(s):

Baylor College of Medicine, HCHD: Harris County Hospital District Ben Taub, HCHD: Harris County Hospital District Community Health Clinics, and Texas Children's Hospital- Women's Pavilion.

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 Baylor College of Medicine 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 Baylor College of Medicine 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 shows what additional samples will 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.

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. Once the DNA sequence test is carried out, computers will be used to compare your sequence to the DNA sequence of the human genome that is in the National Library of Medicine. This will identify the mutations that are in your genome.

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. 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.

If you are an individual with pre-diabetes (“at increased risk for diabetes”), your DNA may be used for DNA sequencing of your whole genome.

Who will have access to my genetic information?

In order to speed research, other researchers would like to have access to your genetic information so that they can compare it to the genetic information of others, from other research studies, and use it to answer future research questions. This information is most valuable when it is linked to information about your medical history (clinical information).

De-identified parts of your genetic information and clinical information obtained during the D2d study, will be with other qualified researchers. This will help advance medicine and medical research by allowing other researchers to use this information to help solve questions of what causes certain diseases.

If you consent to the de-identified release of your DNA sequence information there may be a privacy risk to you. Nobody will be able to know just from looking at a database that the information belongs to you. However, because your genetic information is unique to you, there is a chance that someone could trace the information back to you or your close biological relatives. The current risk of this happening is very small, but may grow in the future. As technology advances, the information in these databases will become more valuable to scientists, but there may also be new ways of tracing the information back to you or your close biological relatives, increasing the risk over time that your privacy would be breached. With restricted databases, researchers who access your genetic and clinical information will have a professional obligation to protect your privacy and maintain your confidentiality.

Will I get to see the results of my DNA analysis?

No. 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.

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_____

PRIVACY AND CONFIDENTIALITY

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. 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 scientists will have some information about you, for example, age, gender, race, medical history and the results of the D2d study. Additionally, 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.

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.

Research related health information

Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study

If you sign this document, you give permission to people who give medical care and ensure quality from Baylor College of Medicine, HCHD: Harris County Hospital District Ben Taub, HCHD: Harris County Hospital District Community Health Clinics, and Texas Children's Hospital- Women's Pavilion to use or disclose (release) your health information that identifies you for the research study described in this document.

The health information that we may use or disclose (release) for this research includes:

- Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.
- Demographic information (name, D.O.B., age, gender, race, etc.)

The health information listed above may be used by and or disclosed (released) to researchers, their staff and their collaborators on this research project, the Institutional Review Board, Baylor College of Medicine, HCHD: Harris County Hospital District Ben Taub, HCHD: Harris County Hospital District Community Health Clinics, Texas Children's Hospital- Women's Pavilion, and NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES (NIDDK) and their representatives.

Agents of the U.S. Food and Drug Administration may inspect the research records including your health information. Agents of regulatory agencies such as the U.S. Department of Health and Human Services will be permitted to inspect the research records including your health information.

The data coordinating center will have access to the research records including your health information.

A Data and Safety Monitoring Board will have access to the research records including your health information.

Use or Disclosure Required by Law

Your health information will be used or disclosed when required by law.

Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability and conducting public health surveillance, investigations or interventions.

Baylor College of Medicine, HCHD: Harris County Hospital District Ben Taub, HCHD: Harris County Hospital District Community Health Clinics, and Texas Children's Hospital- Women's Pavilion are required by law to protect your health information. By signing this document, you authorize Baylor College of Medicine, HCHD: Harris County Hospital District Ben Taub, HCHD: Harris County Hospital District Community Health Clinics, and Texas Children's Hospital- Women's Pavilion to use and/or disclose (release) your health information for this research. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.

Please note that the research involves treatment. You do not have to sign this Authorization, but if you do not, you may not receive research-related treatment. To maintain the integrity of this research study, you generally will not have access to your personal health information related to this research until the study is complete. However, your health information that is necessary to your care

will be provided to you or your physician. At the conclusion of the research and at your request, you generally will have access to your health information that Baylor College of Medicine, HCHD: Harris County Hospital District Ben Taub, HCHD: Harris County Hospital District Community Health Clinics, and Texas Children's Hospital- Women's Pavilion maintain in a designated record set, which means a set of data that includes medical information or billing records used in whole or in part by your doctors or other health care providers at Baylor College of Medicine, HCHD: Harris County Hospital District Ben Taub, HCHD: Harris County Hospital District Community Health Clinics, and Texas Children's Hospital- Women's Pavilion to make decisions about individuals. Access to your health information in a designated record set is described in the Notice of Privacy Practices provided to you by representatives of the specific institution where you are being enrolled into this research study which are: Baylor College of Medicine, HCHD: Harris County Hospital District Ben Taub, HCHD: Harris County Hospital District Community Health Clinics, and Texas Children's Hospital- Women's Pavilion.

Please note that you may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, researchers, their staff and their collaborators on this research project, the Institutional Review Board, NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES (NIDDK) and their representatives, regulatory agencies such as the U.S. Department of Health and Human Services, FDA, Baylor College of Medicine, data coordinating center, Data and Safety Monitoring Board, HCHD: Harris County Hospital District Ben Taub, HCHD: Harris County Hospital District Community Health Clinics, and Texas Children's Hospital- Women's Pavilion may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. If you revoke this Authorization, you may no longer be allowed to participate in the research described in this Authorization.

To revoke this Authorization, you must write to: John Foreyt, PhD
6655 Travis Suite 320
Houston, Tx 77030

This authorization does not have an expiration date. If all information that does or can identify you is removed from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.

No publication or public presentation about the research described above will reveal your identity without another authorization from you.

Potential Risks and Discomforts
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.

Study staff will update you in a timely way on any new information that may affect your decision to stay in the study. There is a small risk for the loss of confidentiality. However, the study personnel will make every effort to minimize these risks.

Potential Benefits

You will receive no direct benefit from your participation in this study. However, your participation may help the investigators better understand prediabetes and medical problems and may benefit the future health of the community at large or a particular patient group. In addition, your participation may help investigators better understand the genetic basis of your disease. This study may result in technological and scientific advancements that may benefit others in the future.

Alternatives

The following alternative procedures or treatments are available if you choose not to participate in this study: continue participating in the D2d study. If you choose to participate in the repository study you may choose to: (1) only donate blood and urine or (2) donate blood, urine and DNA..

Investigator Withdrawal of Subject from a Study

The investigator may withdraw you from the study for a safety reason.

The investigator or sponsor may decide to stop you from taking part in this study at any time. You could be removed from the study for reasons related only to you (for example, if you move to another city, if you do not take your D2d study medication, or if you have a serious reaction to your study medication) or because the entire study is stopped. The sponsor, investigator, Food and Drug Administration, or Institutional Review Board may stop the study at any time.

Subject Costs and Payments

You will not be asked to pay any costs related to this research.

You will not be paid for taking part in this study.

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.

In the event of injury resulting from this research, (your HCHD institution) and/or the Harris County Hospital District are not able to offer financial compensation nor to absorb the costs of medical treatment. However, necessary facilities, emergency treatment and professional services will be available to you, just as they are to the general community.

Research personnel will try to reduce, control, and treat any complications from this research. If you are injured because of this study, you will receive medical care that you or your insurance will have to pay for just like any other medical care.

Subject's Rights
Your signature on this consent form means that you have received the information about this study and that you agree to volunteer for this research study.

You will be given a copy of this signed form to keep. You are not giving up any of your rights by signing this form. Even after you have signed this form, you may change your mind at any time. Please contact the study staff if you decide to stop taking part in this study.

If you choose not to take part in the research or if you decide to stop taking part later, your benefits and services will stay the same as before this study was discussed with you. You will not lose these benefits, services, or rights.

The investigator, JOHN P FOREYT, and/or someone he/she appoints in his/her place will try to answer all of your questions. If you have questions or concerns at any time, or if you need to report an injury related to the research, you may speak with a member of the study staff: JOHN P FOREYT at 713-798-3839 during the day and Charlyne Wright, R.N. 713-798-6476 after hours.

Members of the Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals (IRB) can also answer your questions and concerns about your rights as a research subject. The IRB office number is (713) 798-6970. Call the IRB office if you would like to speak to a person independent of the investigator and research staff for complaints about the research, if you cannot reach the research staff, or if you wish to talk to someone other than the research staff.

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 Principal Investigator at: John P. Foreyt, Behavioral Medicine Research Center, Baylor College of Medicine, 6655 Travis St., Suite 320, Houston, TX 77030, 713-798-5757, 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.

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.

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

Subject	Date
Investigator or Designee Obtaining Consent	Date
Witness (if applicable)	Date
Translator (if applicable)	Date