Wake Forest™ Baptist Health

The Diabetes Heart Study

Informed Consent Document

Project Title: A Study of Diabetes and Heart Disease

Principal Investigator: Donald W. Bowden, Ph.D.

Clinical Director: Barry I. Freedman, M.D.

Purpose
This is a research study of diabetes and heart disease. High blood sugar (glucose) levels for a long period of time in people with diabetes can cause significant problems, particularly heart disease. Heart disease is a common problem of diabetes. You have participated in earlier phases of the Diabetes Heart Study and you are again being asked to participate in this study aimed at understanding factors which lead to diabetes and heart disease. You have been invited to participate in this study because you have diabetes and previously participated in the Diabetes Heart Study. Approximately 100 participants will be enrolled in this single center study at Wake Forest School of Medicine.

Your participation is voluntary. You may refuse to participate, or withdraw your consent to participate in any study at any time and for any reason. This will not affect your future care at this institution or your relationship with your doctor. You do not have to participate in research in order to receive treatment.

Details about this study are discussed below. It is important that you understand this information so that you can decide in a free and informed manner whether you want to participate. You will be given a copy of this consent form. You are urged to ask the investigator named above, or staff members who may assist them, any questions you have about this study at any time. You may also discuss the study with your friends and family.

Procedures
If you take part in this study, you will have the following tests and procedures:

- You will be asked to provide information from your health record such as age, sex, ethnic background, medical history, current medications, diet, exercise habits and medical care.

- A brief physical exam will be performed that includes measures of your height, weight, and blood pressure.

- You will be asked to provide a urine sample for measures of protein in the urine and kidney disease.

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- You will be asked to have a Computed Tomography (CT) scan to measure calcium in the blood vessels of your heart. This test will be in the Radiology Department. You will lie on your back on a special table that is part of the CT scanner. Electrocardiogram (ECG) leads will be attached to your body. The table will move into the CT scanner, which is shaped like a large doughnut. You will be asked to take several deep breaths and then hold your breath for 24-45 seconds during the scans. Studies of your heart, neck and abdomen will be made. No needles are used, the skin is not broken, and there is no discomfort associated with this procedure. You will not need to take anything by mouth or by injection and the exam takes about 20 minutes to complete. The CT scan will be used to determine if the amount of calcium in your blood vessels has changed since your prior examination in the DHS.

- You will be asked to provide a blood sample (approximately 6.32 tablespoons or 93.5 ml), which will be taken from a vein in your arm. The levels of lipids (fats and cholesterol) and blood sugar will be measured. In addition the levels of chemicals that are thought to be associated with heart disease will be measured. Knowing some background information about you will help us understand how the findings of this study relate to diabetes.

Length of Study

It will take approximately 2 hours to complete all of the study related procedures listed above. You may be asked to return to clinic at a later date in case of mechanical failure or if your study visit is incomplete for any reason.

Storage of Biological Specimen

If you agree to participate in this study, a portion of your blood and urine samples may be stored for future research. These samples will be kept and may be used in future research to learn more about other diseases. Your samples will be obtained in the Clinical Research Unit (CRU) at Wake Forest University Baptist Medical Center. The samples will be stored in the laboratory of Dr. Bowden in the Nutrition Research Center for Human Genomics and will be given only to researchers approved by Dr. Bowden. An Institutional Review Board (IRB) must also approve any future research study using your specimens.

Your blood and urine samples will be stored with a unique identifier and will not include any identifiable information about you such as your name, address, telephone number, social security number, medical record number or any of the identifiers outlined in the HIPAA Privacy Rule. The unique identifier will be a randomly assigned number and only the principal investigator will have access to the code that links the unique identifier to you. Your name, address, social security number, etc., will never be disclosed to future researchers and neither will the code that links your identifiers to the sample.

The research being done with your blood is not designed to help you specifically. There is no personal benefit to you from taking part in this research study. It might help people who have diabetes or other diseases in the future, but it is not known if this will happen. Because it is not known how the results of this research study relate to your individual health, the results of the research done with your blood will not be given to you or your doctor without your permission. These results will not be put in your health records. This research will not affect your care at the Wake Forest Baptist Medical Center. This research may provide information about diseases that are passed on in families.

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Because it is not yet known how the results of this study relate to the health of members of your family, the results will not be provided to your family members.

Your blood sample will be used only for research and will not be sold. The findings from this research may result in the future development of products that are of commercial value. There are no plans to share any of the profits with you which may occur as a result of this research.

In the future, researchers may need to know more about your health. Dr. Bowden may give them reports about your health but they will not be given your name, address, phone number or any other information about who you are unless you agree to being contacted in the future.

You may not participate in this study if you do not agree to the information regarding the use of your blood and health records as stated above.

In addition, as part of the Diabetes Heart Study, we may have previously collected data and are continuing to collect data on the organization of your genes and how they are inherited. As part of genetic study, a sample of your DNA may have Genome Wide Association analysis (GWAS) done on it. This analysis creates a very detailed picture of your DNA for researchers. If this is performed, information regarding your DNA and clinical information about you will be sent to the National Institute for Health's Genome Wide Association Study (GWAS) data repository, where it may be shared with other investigators for research purposes. This GWAS information will help researchers better understand how genes affect the risk of developing diseases such as asthma, cancer, diabetes, and heart disease, and may lead to better methods to select the best treatment options. Before your information is sent to the GWAS data repository it will be de-identified, which means that we will remove any identifying information such as your name, date of birth, address, etc. Thus, researchers using your DNA and clinical data will not be able to link this information back to you.

Risks

You may experience discomfort, bruising, and/or bleeding where the needle is inserted for the blood collection. Occasionally some people become dizzy, lightheaded or feel faint. Infection may occur on rare occasions.

This research involves exposure to radiation from the computed tomography (CT). The risk from this procedure is small. The amount of radiation exposure that you will receive from this procedure is equivalent to a uniform whole body exposure of 1100 millirem or 11 mSv (range 5 to 16 mSv). This is equal to 3.7 times the amount of background radiation that the average person in the United States receives each year (annual background = 300 millirem). There are no other known risks associated with the procedure.

Because of the radiation exposure, pregnant women are excluded from this study. All subjects of childbearing potential will be provided a pregnancy test prior to initiating the study to confirm that pregnant women are not included.

Please be aware that this radiation exposure is necessary for this research study only and is not essential for your medical care. Wake Forest Baptist Health's Radiation Safety Committee, a group of experts on radiation matters, have reviewed the use of radiation in this research study and have approved this use as being necessary to obtain the research information desired. The potential long-term risk from these radiation

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doses is uncertain, but exposures at these levels to medical radiation have never been associated with any definite adverse effects. Thus, the risk to you, if any, is estimated to be slight.

Potential Benefits
Participation in this study will provide information about heart disease and diabetes that is important to the general medical community. Your study results including cholesterol, blood sugar, urinalysis and CT scan will be shared with you and your primary doctor, with your permission. If something important is found on your CT scan, the information will be available to you at your request. It is your responsibility to pursue further evaluation and treatment should that be necessary and any associated costs will not be covered by this study. If you elect not to share test results with your doctor, you will be informed if abnormalities are detected and advised to seek further medical care.

Alternatives
This is not a treatment study. You do not have to participate in this research study. Choosing not to participate will in no way affect your care at this institution or your relationship with your doctor.

Costs
There are no costs to you for taking part in this study. All examination and laboratory testing will be performed without charge. Cost for your regular medical care, which is not related to this study, will be your own responsibility.

Compensation
You will receive $100 reimbursement for your time and travel for participating in this study. To receive payment you must provide your social security number, name and address so that we can comply with IRS (Internal Revenue Service) reporting requirements. When payments are reported to the IRS we do not let them know what the payment is for, only that you have been paid. If you do not wish to provide this information you can still take part in this study but you will not be paid.

Who Is Sponsoring This Study?
This study is being sponsored by the National Institutes of Health. The sponsor is providing money or other support to Wake Forest Health Sciences to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor.

Use, Disclosure and Confidentiality of your Health Information
In this research study, any new information we collect from you or information we get from your medical records about your health or behaviors is considered Protected Health Information. The information we will collect for this research study may include**:** A brief physical exam that includes measures of your height, weight, blood pressure and questions about your general health. You will be asked to provide information from your health record such as age, sex, ethnic background, medical history, current medications, diet and exercise habits. A blood sample will be taken to measure the levels of lipids (fats and cholesterol), blood sugar and kidney function. A urine sample will be taken for measures of protein in the urine and kidney disease. You will be asked to complete a Computed Tomography (CT) scan to measure calcium in the blood vessels of your heart, neck and abdomen.

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If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study may be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with Medical Center operations.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer. Only the following people or organizations will be granted access to your Protected Health Information:

1) The study investigator and his/her staff, or others at Wake Forest University Health Sciences who oversee research

2) Other people or laboratories providing services for this research project on behalf of Wake Forest University Health Sciences and Wake Forest University Baptist Medical Center

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it might no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study will be kept in the research records for at least six years after the study is finished. At that time any research information not already in your medical record will either be destroyed or it will be de-identified. Any research information entered into your medical record will be kept for as long as your medical record is kept by the Medical Center. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.

You can tell Donald W. Bowden, Ph.D. that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Donald W. Bowden, Ph.D.
Center for Human Genomics
Wake Forest School of Medicine
Medical Center Blvd.
Winston-Salem, NC 27157-1053

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your Protected Health Information for this study.

A North Carolina Baptist Hospital (NCBH) medical record will be created for all study participants. Information about your participation in the study will be placed in the NCBH medical record, along with any routine medical test results that were obtained at NCBH as part of this study.

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Research-related Injury
Should you experience a physical injury or illness as a direct result of your participation in this study, Wake Forest School of Medicine maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of such injuries or illnesses. To the extent research insurance coverage is available under this policy the reasonable costs of these necessary medical services will be paid, up to a maximum of $25,000. Wake Forest Baptist Medical Center holds the insurance policy for this coverage. It provides a maximum of $25,000 coverage for each claim, and is limited to a total of $250,000 for all claims in any one year**.** The Wake Forest School of Medicine, and The North Carolina Baptist Hospitals, Incorporated do not assume responsibility to pay for these medical services or to provide any other compensation for such injury or illness. Additional information may be obtained from the Medical Center's Director of Risk and Insurance Management, at (336) 716-3467.

If you are injured, the insurer may require information such as your name, social security number and date of birth in order to pay for your care. This is because the insurer is required by law to report any payments made to cover the care of any persons who are members of a government insurance plan to the Department of Human and Health Services.

You do not give up any legal rights as a research participant by signing this consent form. For more information on medical treatment for research related injuries or to report a study related illness, adverse event or injury you should call Barry I. Freedman, M.D. at 336-716-6192 or (fax) 336-716-4650.

Participant's Rights
Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. You can have your blood and information withdrawn from the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled nor will it affect any subsequent patient care at this institution.

Request for More Information
For questions about this study or in the event of a research-related injury, contact the clinical director Dr. Barry I. Freedman, M.D. at 336-716-6192.

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at (336) 716-4542.

Subject Consent
I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the

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sponsor, the institution or its agents from liability for negligence.

Please read each of the following sentences and think about your choices. After reading each sentence, circle YES or NO. If you have questions, please talk to your doctor or nurse.

You agree that your blood and health records may also be kept for use in future research to learn about, detect, prevent, treat or cure other health problems. If you answer NO to this question, you may no longer participate in this study.

YES **NO**

You agree that Dr. Bowden, or someone he chooses, may contact you in the future to ask taking part in more research. If you answer NO to this question, you may still participate in this study.

YES **NO**

You would like to know the results of your cholesterol, blood sugar, urinalysis and CT scan and have this information provided to your doctor. If you answer NO to this question, you may still participate in this study.

YES **NO**

_____
Subject Name (Printed)

_____ _____ _____
Subject Signature Date Time am/pm

_____ _____ _____
Person Obtaining Consent Date Time am/pm

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