Wake Forest®
School of Medicine

Department of Epidemiology and Prevention

# HEALTHY LIVING PARTNERSHIPS TO PREVENT DIABETES IN VETERANS

Informed Consent Form to Participate in Research

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## INTRODUCTION

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you weigh more than is ideal and you may be at risk for developing diabetes. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

## WHY IS THIS STUDY BEING DONE?

The Healthy Living Partnerships to Prevent Diabetes in Veterans, or HELP PD Vets pilot study, will test two strategies to prevent the development of diabetes in Veterans who are overweight and at risk. Previous studies have shown that weight loss has many benefits, including preventing diabetes. Most of these studies have been conducted in strictly research settings using professional staff like dietitians and doctors working one-on-one with participants. We don't know if a group-based program led by a lay (non-professional) person and delivered in a real healthcare setting like the VA would also help people lose weight.

## HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Fifty (50) people from the Kernersville Health Care Center will take part in this study. In order to identify the 50 participants needed, we may need to screen as many as 200 because some people will not qualify to be included in the study.

## WHAT IS INVOLVED IN THE STUDY?

The HELP PD Vets pilot study will consist of two groups of volunteers. You will be randomized into one of the groups described below. Randomization means that you are put into a group by chance. It is like flipping a coin. You will have an equal chance of being placed in either group. Group A will be involved in a weight loss program that combines individual meetings with a registered dietitian with group sessions led by a trained member of the community known as a community health worker. Group B will receive two individual sessions with a registered dietitian and written information about resources for weight loss and healthy living in the local area. Both groups will receive the same medical monitoring.

If you are randomized to Group A, you will receive three individual sessions with a registered dietitian during months 1, 3, and 6 at the Kernersville Health Care Center. You will also meet once a week with a group of other participants and your community health worker for 6 months. These meetings will take place at a local location that is convenient for your group, like a church or community center. Information about diet, exercise, and weight loss will either be delivered by your community health worker, an expert from the community, or by a DVD presentation. As a part of this group, you will be asked to start your own walking or other exercise program and to make changes to the food you eat. You will also be asked to write-down the type and amount of foods you eat and the number of minutes you walk or do other exercise each day.

If you are randomized to Group B, you will have two individual meetings with a registered dietitian at the Kernersville Health Care Center during the first three months of the study and then you will be given information on a variety of community programs. You will also receive a newsletter monthly with information about healthy living. At the end of the study, we will share the information we have learned about successful strategies to change lifestyle and reduce the risk of developing diabetes with you.

If you take part in this study, we will collect some information from your doctor and your medical record about your health. We will collect:

- Results from recent bloodwork including glucose (blood sugar), cholesterol, and triglycerides
- Medical history and information about your health behaviors like diet and exercise
- Information about your health-related quality of life
- Information about your use of healthcare and other resources

If you decide to participate, you will also complete a baseline visit and a 6-month visit. Both of these visits will be conducted in the Kernersville Health Care Center. During these visits, we will measure or collect:

- Height and weight
- Waist circumference or waist size
- Blood pressure and pulse
- Information about your health behaviors like diet and exercise and health-related quality of life

## HOW LONG WILL I BE IN THE STUDY?

You will be in the study for about 6 months.

You can stop participating at any time. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences.

## WHAT ARE THE RISKS OF THE STUDY?

Being in this study involves some risk to you. You should discuss the risk of being in this study

with the study staff. Risks and side effects related to participating in this study include:

Risks of Increasing Physical Activity: Increasing your physical activity may increase your risk of injuries to the muscles, ligaments, tendons and joints of the body. Other risks include abnormal blood pressure, fainting, dizziness, disorders of heart rhythm, and very rare instances of heart attack, stroke, or even death. To help ensure your safety, the study will check your readiness to become more active. A study doctor will see you if your readiness is in doubt.

Risks of Hypotension (Low Blood Pressure): If you do lose weight while you take medicines to control your blood pressure, there is a chance you may have episodes of feeling light-headed, dizzy or nauseous from a drop in blood pressure. Low blood pressure is also known as hypotension. To reduce the chance of hypotension, please report any feelings dizziness, nausea, or light-headedness to study staff. If you develop low blood pressure, the study doctors will contact your doctor to discuss adjustment of your blood pressure medicine.

Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

## REPRODUCTIVE RISKS TO PARTICIPATING IN RESEARCH

Due to unknown risks and potential harm to the unborn fetus, sexually active women of childbearing potential must use a reliable method of birth control while participating in this study. Reliable methods of birth control are: abstinence (not having sex), oral contraceptives, intrauterine device (IUD), DepoProvera, tubal ligation, or vasectomy of the partner (with confirmed negative sperm counts) in a monogamous relationship (same partner). An acceptable, although less reliable, method involves the careful use of condoms and spermicidal foam or gel and/or a cervical cap or sponge. We encourage you to discuss this issue further with your physicians if you have any questions.

Pregnant women are excluded from participation in this study. If you are a sexually active woman of childbearing potential and have not been using a reliable method of birth control, two negative pregnancy tests performed 15 days apart are required to check for possible early pregnancy prior to starting treatment.

## ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may or may not be direct benefit to you. We hope the information learned from this study will benefit other people in the future. The benefits of participating in this study may include losing weight, a decrease in your risk for developing diabetes or cardiovascular disease, and improvements in your quality of life.

## WHAT OTHER CHOICES ARE THERE?

This is not a treatment study. Your alternative is to not participate in this study.

## WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you and information we get from your medical records or other facilities about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes height, weight, waist circumference, blood pressure, laboratory results, and information about your medical history, health behaviors, and health-related quality of life.

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
3) Investigators and staff at the Department of Veteran's Affairs who are affiliated with the study team.

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 may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept 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. This authorization does not expire and 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 Dr. Mara Vitolins 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:

*Mara Z. Vitolins, DrPH, MPH, RD*
[redacted]

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 description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this Web site at any time.

## WHAT ARE THE COSTS?

There are no costs to you for taking part in this study. All study costs, including any study medications and procedures related directly to the study, will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

## WILL YOU BE PAID FOR PARTICIPATING?

You will receive a $25 gift card for completing your baseline visit and your 6-month visit. Both of these visits will be conducted in the Kernersville Health Care Center.

## WHO IS SPONSORING THIS STUDY?

This study is being sponsored by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), part of the National Institutes of Health. The sponsor is providing money or other support to Wake Forest University Health Sciences to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

## WHAT HAPPENS IF YOU EXPERIENCE AN INJURY OR ILLNESS AS A RESULT OF PARTICIPATING IN THIS STUDY?

Should you experience a physical injury or illness as a direct result of your participation in this study, Wake Forest University 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 University 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 University 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 [redacted].

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 Health and Human 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 Dr. Mara Vitolins at [redacted] or [redacted] after hours.

## WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or you may leave 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. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because it is in your best medical interest, new information becomes available, you failed to follow instructions, or because the entire study has been stopped. You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

## WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study investigator, Dr. Mara Vitolins, at [redacted] or the Project Manager, Caroline Blackwell, at [redacted]. After hours, please call Dr. Mara Vitolins at [redacted].

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 [redacted].

You will be given a copy of this signed consent form.

## SIGNATURES

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

Subject Name (Printed):_____

Subject Signature: _____ Date: _____Time:_____ am pm

Person Obtaining Consent:_____ Date:_____ Time:_____ am pm