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Official Title: Dissemination of a Diabetes Prevention Program Among Medicare Eligible Retirees

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University of Pittsburgh

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Consent to Participate in a Research Study

Dear Medicare Participant,

Study description. Dr. Elizabeth M. Venditti and her research team from UPMC and the Graduate School of Public Health has partnered with the University of Pittsburgh Human Resources Benefits Department to offer Medicare-eligible individuals the Group Lifestyle Balance™ program, as part of a new research study beginning January, 2013. Group Lifestyle Balance™ is a one-year community intervention program that will provide eligible participants with 12 weekly in-person group sessions followed by monthly contacts for the remainder of one year. The purpose of the program is to provide you with support for making healthy changes in diet and physical activity in order to reduce your risk for Type 2 diabetes and cardiovascular disease. We plan to enroll 320 Medicare participants from the Tri-State area. Participation in this research study is completely voluntary and the choice is yours.

Randomization. After completing the 12 weekly in-person group sessions, we want to look at which of two types of continued monthly contacts (either mailed newsletters or telephone calls), is more effective in helping you maintain your lifestyle changes and related health outcomes. If you consent to take part in this study you will be assigned randomly (by chance) to one of the two follow-up contact conditions. This type of lifestyle intervention program is not widely available in the Medicare community and the research is being done to understand more about how to best provide these kinds of services.

Assessment activities. If you are determined to be eligible for this project and wish to take part in the Group Lifestyle Balance™ intervention program you will be asked to participate in research assessments of your height, weight, waist circumference, fasting blood work, and blood pressure as well as answer some other questions about your health and well-being and medical care. You will also be asked to take part in a short physical performance assessment that is related to the functional ability and independence of older adults. These measurements will take place mostly according

to the following schedule: baseline (0), 4, 12, and 24 months. If you are unable to attend one of these visits you will be contacted by telephone to collect research information or be asked to complete surveys and questionnaires and return them by mail. The assessments include the following:

Height, weight, waist measurement (a tape measure is placed around your waist and two separate measurements are recorded). Blood pressure will be taken twice in your arm after resting for five minutes (using an automated blood pressure cuff). Blood sample will be taken by a prick of the finger (less than one teaspoon). You will be asked not to eat or drink anything except water for at least 8 hours prior to the test. The blood will be tested right away for sugar (glucose), fats (lipids including cholesterol and trigylcerides). Short physical performance assessment includes a measure of your grip strength, your balance, your gait speed, and ability to get up and down from a chair. Other questionnaires and surveys include a demographic and medical history (less than 10 minutes), nutrition surveys (about 10 minutes), a physical activity survey and questions about your past month activity level (about 15 minutes), a mental health and well-being measure (about 2 minutes), questions about mood (less than 10 minutes), and a survey asking how you might respond when faced with important life problems (about 10 minutes). You will also be asked some questions about your medical and hospital visits, the medications you take, your history of falls, and your satisfaction with the Group Lifestyle Balance™ intervention program.

Intervention Activities: Months 1-4. In the Group Lifestyle Balance™ program you will be asked to take part in 12 weekly in-person group sessions. Sessions last approximately one-hour and are conducted in groups of roughly 10-15 people. The goal of the program is to help you lose a modest amount of weight (about 5-7% of your bodyweight on average) and slowly and progressively increase your physical activity to 150 minutes per week. You will be asked to keep a record of your food intake and your physical activity and you will be weighed at each session. A “lifestyle coach” (a trained individual with experience in helping people make healthy lifestyle changes to prevent or delay risk factors for diabetes) will lead the group sessions. If you choose to take part you will be encouraged to attend as many sessions as possible and discuss your experiences during the group sessions. A focus of most sessions is problem solving for common barriers or challenges to developing a healthier lifestyle.

Intervention Activities: Months 5-12. In the follow-up portion of the Group Lifestyle Balance™ program you will be randomly assigned (by chance) to one of two types of continued monthly contacts (either mailed newsletters or telephone calls) for the remainder of one year. If you are assigned to the telephone call follow-up you will be given a scheduled time to participate for about 30 minutes, once per month. These will most often be group calls (about five people) but individual calls may also be used to accommodate participant needs and schedules. You will not be responsible for any

costs related to these calls however you will need to have a phone line available for this purpose (including assistive listening devices if needed). Phone sessions will be similar to in person group sessions in that your lifestyle coach will present either new or expanded material to reinforce the principles learned during the first 12 sessions. You will be encouraged to share information about the barriers you are experiencing with respect to your diet, activity and weight loss goals and the strategies you have been using to work towards these goals. You will be asked to continue monitoring your food intake, physical activity and weight and to share that information with your lifestyle coach (separately via USPS mail, e-mail, or voice-mail). However, you will not be asked to report this data on the call. Rather the overall purpose of the calls is to do group problem-solving for common barriers, planning ahead for future challenges, and to offer each other continued social support.

Health Care Provider (HCP) Permission to Participate Referral Form. The activity goal for the Group Lifestyle Balance™ program is a minimum of 150 minutes per week of activity akin to brisk walking. This means working towards about 30 minutes of physical activity on five days of the week and decreasing the amount of sedentary time in your daily lifestyle routine. The activity goals are consistent with the recommendation of the Surgeon General and other major health organizations for the general public. In order for you to work safely towards the activity goals prescribed by the program, we must be sure that your physician or HCP approves of your participation by signing the appropriate section on the referral form for moderate physical activity.

Health Care Provider (HCP) Documentation of Risk Factors for Type 2 Diabetes and Heart Disease. The HCP referral form also has a section to document specific risk factors for diabetes or cardiovascular disease. If you are not aware of whether or not you have risk factors for Type 2 diabetes or heart disease other than overweight or obesity you can ask your HCP to document this information on your permission to participate form. This form also describes the purpose and procedures of the Group Lifestyle Balance™ program so that you may discuss whether or not this is the appropriate healthy lifestyle program for you at this time.

Possible risks associated with assessment activities.
Fingerstick blood draw -- temporary discomfort including possible bruising or redness of the skin, lightheadedness, and on very rare occasion infection. Body measurements -- embarrassment associated with measurements of weight and waist. Surveys and questionnaires -- minor discomfort answering questions that are personal in nature. Physical function tests -- some lightheadedness or imbalance with gait and balance tests, muscle strain or soreness with the grip strength test, or a rare risk of injury or joint discomfort with any the physical function tests. After demonstration by staff if you feel that any of the motor movements, such as walking, hand gripping a measuring

device, or rising up from a chair several times may be unsafe, you may choose not to do them. Other. There is a rare risk that a breach of confidentiality could occur; however, every effort is made to prevent this from happening. In addition, every effort is made to perform assessment activities in a private and respectful manner by research staff who have been specifically trained to do them.

Possible benefits of assessment activities. You will likely receive no direct benefit from these measurements beyond receiving notification of your results.

Possible risks associated with intervention activities. Modest weight loss is associated with a few risks. It is common or likely for participants to experience hunger, lightheadedness, and/or constipation when reducing their calorie intake. However this program recommends a healthy balanced diet, rich in plant based foods, and a regular pattern of meals and snacks (consistent with national dietary recommendations), which may reduce this risk. The risks associated with exercise occur occasionally (1-10% or 1-10 people in 100) and include fatigue, muscle soreness, and injury such as sprained ankles or pulled muscles. Risks are reduced by proper warm-up and cool-down periods. There may be additional risk of heart problems for those who have a chronic disease or experience symptoms with exercise, although this risk is extremely minimal given the intensity of the recommended exercise, i.e., walking. The level of activity that we will recommend for you is thought to be more helpful than harmful, but there is a very small risk of heart attack or sudden death during exercise. Heart attack has been estimated to occur less than once out of 500,000 hours of exercise in people without known heart disease. The risk is greater in people with heart disease. It is important that you contact your physician or HCP before increasing the intensity of your physical activity program or if you develop diabetes, heart disease or other related health problems during this study.

Possible benefits of these intervention activities. You may not receive any benefit from these intervention activities. If successful in the lifestyle program, you may lose weight and/or reduce the level of one or more diabetes/heart disease risk factors. Your participation in this research may benefit society by enhancing our understanding of the lifestyle intervention procedures and practices that are associated with reduced risk for diabetes and heart disease and improved health and well being in older adults.
Other treatments in the community. Whether you participate or not has no effect on your Medicare benefits or your usual medical care. You may seek other weight loss and exercise programs available in the community.
Payment for participation in the study. Neither you nor your insurance provider will be charged for any of the assessment or intervention activities delivered in this study. For your time and effort and to help defray your transportation costs you will be reimbursed for completion of assessment visits according to the following schedule: $25 at 0 (baseline) and 4 months; $50 at 12 months; $75 at 24 months.

Injury as a result of taking part in this study. If you believe that research procedures have resulted in an injury to you, immediately contact Dr. Venditti (contact information below). Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. Your insurance provider may be billed for the costs of this emergency medical treatment but none of the costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care.

Knowledge of my participation in the study/access to my medical information. All records related to your involvement in this study will be kept in a private locked file. Your identity is indicated by a case number and not by name. The information linking case numbers and your name is kept separate from these research records. In addition to the investigators listed below and research staff members, the only individuals who may have access to identifiable information about you are authorized representatives of the University of Pittsburgh Research Conduct and Compliance Office who may monitor the appropriate conduct of this research study. Medical information/test results from this research study can be sent to your physician/HCP only if you authorize it.

Withdrawal from the study. You can stop participating in this study at any time, even after signing this form. To do so, you should contact Dr. Elizabeth Venditti or one of the other investigators listed below. The information that you have provided prior to telling us you have withdrawn, will be retained.

VOLUNTARY CONSENT

The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions, voice concerns or complaints about any aspect of this research study during the course of the study and that such future questions, concerns or complaints will be addressed by Dr. Venditti or a member of her research team. I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator. I understand that I may contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns and questions, obtain information, offer input, or discuss situations in the event that the research team is unavailable. By signing this form I agree to participate in the research study. A copy of this consent form has been given to me.

_____ _____

Participant's Signature Date

_____ _____ _____

Participant's Printed Name Phone Number Best time to call

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CERTIFICATION OF INFORMED CONSENT: I certify that I have explained the nature and purpose of this research study to the above named individual and I have explained the potential benefits of study participation. I further certify that no research component of this protocol was begun until after this consent form was signed. Any question the individual has about the study has been answered, and we will always be available to address future questions as they arise.

_____ _____

Signature of Person Obtaining Consent Role in Research Study

_____ _____

Printed Name of Person Obtaining Consent Date

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Thank you for your time and consideration.

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