NCT #
1-R34-DK-109503-01

IRB Approval Stamp
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Form Revision Date: 12/2015

We invite you to take part in a research project that studies how diabetes patient education can help patients to live better with their diabetes.

Please take your time to read this form, ask any questions you may have and make your decision. We encourage you to discuss this study with your family, friends and your doctor(s).

Agreeing to take part in this research study is entirely voluntary and refusal to participate will in no way affect any rights or benefits you have nor will it affect your care at the MedStar Washington Hospital Center.

As a participant in this study you will be asked to:

- Complete a pre and post diabetes knowledge test
- Watch an educational video on how to take care or your diabetes
- Agree to a follow-up telephone call 2-5 days and 30 days after you leave the hospital.

You will receive a gift card after you complete the 30-day follow-up phone call.

The knowledge gained from your participation in this study may help others with diabetes.

You may stop participation at any time. To do so, please write to Dr. Michelle Magee at the MedStar Diabetes Institute address below. However, any information already obtained from you will be retained as necessary to preserve the integrity of the research study.

You do not need to pay anything to be in this research study. Your personal health information (PHI) will be kept private to the extent allowed by law. You will not be identified by name or other PHI in any publications resulting from this study. Dr. Michelle F. Magee and her staff at MedStar Health (together called "Researchers"), as well as (when applicable) the other people or companies listed below, may receive, use, have and reveal (disclose) your PHI (as permitted below) for the reason(s) related only to this project and as needed to conduct the research. The following entities may review your PHI for reason(s) related to this research study:

- The project sponsor, MedStar Diabetes Institute and National Institute of Health including others working with the Sponsor (together called "Sponsor").
- Laboratories, other individuals and organizations that look at your health information in conjunction with this study;
- Members and staff of the Institutional Review Board and all other review boards or persons who watch over how the research is performed and/or monitor the safety of the research, including the Institution that approves this project;
- The Patient Advocate or Research Ombudsman (people who watch out for your best interest);
- The United States Food and Drug Administration (FDA), any other Federal or State Agency that watches over the safety of the study and how the project is managed or run.

The MedStar Washington Hospital Center, all your doctors and other healthcare providers, and others who generate or use health information, may give your health information in your medical or other records to the Researchers, Sponsor and others listed above, for the research-related activities used in this project and as otherwise described below. You agree to release all your personal information contained in your medical records or other healthcare related records requested by the Researchers to be able to get the data needed for this research study. (*Note: If any of the above records contain any information about HIV/AIDS status, cancer diagnosis, drug/alcohol abuse, sexually transmitted disease, or includes records or information from another healthcare provider, you agree that you are authorizing the release of this information.)

What can happen if you agree to this use or disclosure of your health information?

- This form applies only to data collected that contains information that could be used to identify you; once this information is removed and you can no longer be identified, the data may be used and given by the Researchers and Sponsor to others, including for other research purposes.
- There is a possibility that Federal privacy laws may no longer protect your personal health information from being given to another person and/or company.

If you have any questions regarding this study please feel free to contact the Research Project Staff. Please contact the Office of Research Integrity is you have questions about your rights as a research participant:

Research Project Staff
Address: MedStar Diabetes Institute
Institute
MedStar Washington Hospital Center
100 Irving St., NW, Suite 4107
Washington, DC 20010
Telephone: 202-877-9163

Office of Research Integrity
Address: MedStar Health Research
6525 Belcrest Rd, Suite 700
Hyattsville, MD 20782

Telephone:301-560-2912
Toll Free: 800-793-7175

For questions regarding your medications and treatment, please contact your regular physician directly.

I, the undersigned, have been informed about this study's purpose, procedures, possible benefits and risks, and I have received a copy of this consent. I have been given the opportunity to ask questions before I sign, and I have been told that I can ask other questions at any time. I voluntarily agree to be in this study. I am free to stop participating at any time without need to justify my decision. If I stop being in the project I understand it will not in any way affect my future treatment or medical care. In addition, by signing below I represent and warrant that I have authority to sign this document and authorize the use or disclosure of PHI and that there are no restrictions that would prevent me form authorizing the use or disclosure of this PHI.

_____ _____
Signature of Participant Date

_____
Printed Name of Participant

As a representative of this study, I have explained the purpose, the procedures, the possible benefits and risks that are involved in this research study. Any questions that have been raised have been answered to the individual's satisfaction.

_____ _____

Signature of Person Obtaining Consent Date

_____

Printed Name of Person Obtaining Consent

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