VUMC Institutional Review Board
Informed Consent Document for Research
Support Person Copy

Principal Investigator: Lindsay Mayberry, PhD, MS **Revision Date:** 05/26/2020
Study Title: Mobile Phone Support for Adults and Support Persons to Live Well with Diabetes RCT
Institution/Hospital: Vanderbilt University Medical Center

The following information is provided to inform you about the research project and your participation in it.

Key Information:
The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Key information about this study:
The purpose of this study is to understand how support from family and friends can make it easier to manage diabetes. Your participation can help us learn more about the role family and friends can play in diabetes management.

Participation in this study lasts 15 months and includes completing 4 surveys. You may receive diabetes information via printed materials and/or text messages. If you decide to participate, a computer will put you in one of two groups by chance. You will be in the same group as the person with diabetes who invited you. By putting participants into groups receiving different types of information, we can learn what works best.

Taking part in this study may not personally help you. It may be helpful to your family member/friend if you become more involved in their diabetes self-care. You may also learn more about diabetes. There are some possible risks of participating in the study. You may experience conflict with your friend/family member when you discuss health and health goals. You may be inconvenienced by phone calls or text messages related to your study participation.

If you participate in this study, you will earn up to $120. The amount you earn is based on the number of surveys you complete over the 15 months of participation. You can complete the surveys by mail, phone, or on the Internet.

Your participation in this study is voluntary. You can stop participating at any time. You are participating at the request of your family member/friend. If your family member/friend withdraws from the study or asks us to withdraw you from the study, we will contact you. We will tell this person if you enrolled as his/her support person and if you withdraw from the study. We will not share any other information you give us with this person or anyone else outside the study team.

If you have any questions about this form or about the study at any time, please call **the FAMS team at (615) 997-0737.**

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Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

Purpose of the study
You are asked to participate in a research study called the FAMS Study. It is led by Dr. Lindsay Mayberry. The purpose is to understand how support from family and friends can make it easier to manage diabetes. Your participation can help us learn more about the role family and friends can play in diabetes management.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether you still want to be in this study.

Procedures to be followed and approximate duration of the study:
Participation in the study lasts 15 months and includes:

- **Surveys:** We will ask you to complete 4 surveys, once about every 3 months. Surveys take about 30 minutes each. They can be completed online, by mail, or over the phone. Surveys collect basic information about you and your involvement in your family member's/friend's diabetes self-care.

- **You may receive diabetes information via printed materials and/or text messages.** If you decide to participate, a computer will put you in one of two groups by chance (like flipping a coin). You will be in the same group as the person with diabetes who invited you. If you receive text messages, we will not send you more than 2 messages a day. By putting participants into groups, we can learn what works best.

Expected costs:
If you do not have a cell phone plan with unlimited calls and/or text messaging, you may have to pay for calls and texts related to this study.

Description of the discomforts, inconveniences, and/or risks that can be reasonably expected as a result of participation in this study:
- You may feel nervous or anxious about answering certain survey questions.
- You may feel annoyance with text messages you receive or with technical problems in the messaging system.
- The time it takes to participate may be inconvenient for you.
- You may receive a call/text at an inconvenient time of day.
- You may be asked to do more to help your family member/friend with diabetes and you may find this burdensome.
- You may experience increased conflict with your family member/friend.

Good effects that might result from this study:

a) **The benefits to science and humankind that <u>might</u> result from this study.**
Your participation in this study can help us better understand how friends and family members can support people with diabetes.

b) **The benefits you might get from being in this study.**
Taking part in this study may not personally help you. It may be helpful to your family member/friend if you become more involved in their diabetes self-care. You may also learn more about diabetes.

Study Results:
Once the study has been completed and data analyzed, you will receive a letter or email summarizing the main findings of the study. This may be a long time after you complete the study, because we must wait for all participants to finish the study.

Alternative treatments available:
This study does not include a treatment.

Compensation for participation:
If you participate in this study, you will earn up to $120. The amount you earn is based on the number of surveys you complete over the 15 months of participation as shown below:

Enrollment	6 months	9 months	15 months
$30 survey	$30 survey	$30 survey	$30 survey

After you complete each survey, we will mail you a pre-paid debit card. It may take 4-6 weeks for the card to arrive. If you are an employee of VUMC, we will need your employee ID number or social security number (SSN) to pay you. This will not be stored as data but used only to issue your payment.

Circumstances under which the Principal Investigator may withdraw you from study participation:
The Principal Investigator may withdraw you from the study if, during the study, there is information to suggest that you no longer qualify. You are participating at the request of your family member/friend. You may be withdrawn if your family member/friend asks us to withdraw you from the study or if your family/member friend withdraws from the study. If we withdraw you, we will tell you the reason why.

What happens if you choose to withdraw from study participation?
Your participation is completely voluntary. You do not have to answer any questions you do not want to answer. You can choose to stop participating at any time during the study. You can call the study team at (615) 997-0737 to tell us you do not want to participate anymore. We will call you back to discuss and confirm your wishes. We will stop any parts of the study that you request.

Clinical Trials Registry:
A description of this clinical trial will be available on 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 website at any time.

Confidentiality:
We will tell the person who invited you if you enrolled as his/her support person and if you withdraw from the study. We will not share any other information you give us on a survey or by text message with this person or anyone else outside the study team. All efforts, within reason, will be made to keep your personal information in your research record confidential but total confidentiality cannot be guaranteed. Your responses to the survey and any information you share via text message will be assigned a study number with no personal identifying information. All study forms will be labeled with a study number and stored securely. Information entered into our electronic database is password protected and kept on a secure Vanderbilt server for up to 10 years after the study is completed. At that time, all data will be destroyed. Only Dr. Mayberry and approved research staff will have access to this information. Research team members will only access your personal information for necessary study procedures, such as to pay you. Your personal information used for payment will not be linked to your other study information and will be stored securely to protect your privacy. This information will be destroyed at the end of the study.

This study has support from the National Institutes of Health (NIH). Therefore, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means. It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help. Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

Your information may be shared with Vanderbilt or the government, such as the Vanderbilt University Institutional Review Board, the Office for Human Research Protections, and the NIH Health, if you or someone else is in danger or if we are required to do so by law.

Even if you decide to stop participating in the study, your consent for us to use information we collected from you does not expire. If you want us to stop using this information, please contact Dr. Mayberry in writing and let her know that you withdraw your consent. Her mailing address is:

Lindsay Mayberry, PhD, MS
Division of General Internal Medicine & Public Health
Vanderbilt University Medical Center
2525 West End Ave, Suite 450
Nashville, TN 37203

Contact Information:

If you should have any questions about this research study, please feel free to contact the FAMS team at (615) 997-0737.

For additional information about giving consent or your rights as a participant in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to contact the Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.