VUMC Institutional Review Board
Informed Consent Document for Research
Participant Copy

Principal Investigator: Lindsay Mayberry, PhD, MS **Revision Date:** 06/18/2020
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: Identifying a support person to participate with you, 4 surveys, and 5 A1c tests. You may receive diabetes information via printed materials, text messages, and/or phone calls from a study coach. If you decide to participate, a computer will put you in one of two groups by chance. By putting participants into groups receiving different types of information, we can learn what works best. We will collect some information from your electronic medical record such as weight, height, medications, and lab results.

Responding to survey questions and/or receiving diabetes information may help you take better care of your diabetes. 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 $200. The amount you earn is based on the number of surveys and A1c tests you complete over the 15 months of participation. You can complete the surveys by mail, phone, or on the Internet. We will mail you A1c kits for the study. You may have pain, redness, or bruising where the blood is taken when you complete the A1c test. You may have frustration or concern if the A1c result is different than expected.

Your participation in this study is voluntary. You can stop participating at any time. We will ask you to identify an adult to participate in this study with you as your support person. We will tell you if the person you invited enrolls in the study and/or if he or she withdraws from the study.

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. Your medical record will contain a note saying you are in a research study. Anyone you authorize to receive your medical record will also get this information.

Procedures to be followed and approximate duration of the study:

Participation in the study lasts 15 months and includes:

- **Identification of a Support Person:** We will ask you to identify an adult to participate in this study with you as your support person.

- **Surveys:** We will ask you to complete 4 surveys total (one about every 3 months). Surveys take about one hour each. They can be completed online, by mail, or over the phone. Surveys collect basic information about you, including how you take care of your diabetes. The information you provide us is only for research purposes. It will not affect the care you receive at your clinic.

- **A1c Tests:** We will ask you to complete 5 A1c tests total (one about every 3 months). We will mail you an A1c test kit to complete at home. The kit includes instructions and everything you need to collect a small blood sample using a finger stick. You will mail your sample to the lab using an envelope with pre-paid postage. We will share your A1c result with you by texting you a link to a secure portal to view the result. You may also call the study team at (615) 997-0737 to receive your result. This result is for research purposes only. It should not inform any clinical care decisions. In rare instances, the kit result may not be accurate. If your result is very different from a recent A1c from your clinic, please let us know by calling the study team.

- **You may receive diabetes information via printed materials, text messages, and/or phone calls from a study coach.** After you finish your enrollment survey, a computer will put you in one of two groups by chance (like flipping a coin). By putting participants into groups, we can learn what works best. If you receive text messages, we will send you approximately 2 messages a day. We will call you to tell you what type of diabetes information you will receive. You must complete this call to complete your enrollment in the study.

- **Medical Record Review:** We will collect information from your electronic medical record. This includes medications you are prescribed, lab results, existing conditions, weight, and height.

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:

- 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 feel nervous or anxious about answering certain survey questions.
- You may feel annoyed with text messages you receive or with technical problems in the messaging system.
- If you share or lose your phone, texts using the word "diabetes" may disclose to others that you have diabetes.
- You may have some anxiety about the A1c tests or confusion/frustration with the directions in the test kit. You may have pain, redness, or bruising where the blood is taken. You may have frustration or concern if the A1c result is different than expected.
- You may experience distress or conflict associated with discussing diabetes and health goals with family members or friends.
- You may experience physical injury if you choose to increase physical activity during the study.

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 learn how to support others with diabetes in the future.

b) **The benefits you might get from being in this study.**
Responding to survey questions and/or receiving diabetes information may help you take better care of your diabetes. 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 $200. The amount you earn is based on the number of surveys and A1c tests you complete over the 15 months of participation as shown below:

Enrollment	6 months	9 months	12 months	15 months
$15 survey $15 A1c Total: $30	$20 survey $20 A1c Total: $40	$25 survey $25 A1c Total: $50	$20 A1c Total: $20	$30 survey $30 A1c Total: $60

After you complete each survey and A1c test, 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 we are unable to contact you to tell you which group you have been randomly assigned to. You may also be withdrawn if, during the study, there is information to suggest that you no longer qualify. 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. If you decide to stop participating in the study, this will not affect the care you receive at your clinic.

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:
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 or over the phone will be assigned a study number with no personal identifying information 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 National Institutes of Health, if you or someone else is in danger or if we are required to do so by law.

Privacy:
Authorization to Use/Disclose Protected Health Information

- What information is being collected, used, or shared?
  To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Vanderbilt University Medical Center and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

- Who will see, use or share the information?
  The people who may request, receive or use your private health information include the researchers and their staff. Additionally, we may share your information with other people at Vanderbilt, for example if needed for your clinical care or study oversight. By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

- Do you have to sign this Authorization?
  You do not have to sign this Authorization, but if you do not, you may not join the study.

- What if you change your mind?

You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

Principal Investigator mailing address:

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.