CT #: NCT05098743
Title: The Influence of a Medication Adherence Smartphone Application on Medication Adherence in Chronic Illness
Informed Consent: October 20, 2021

VUMC Institutional Review Board
Informed Consent Document for Research

Principal Investigator: Christa Hartch **Revision Date: 10-20-2021**
Study Title: The Influence of a Medication Adherence Smartphone Mobile Application on Medication Adherence in Chronic Illness
Institution/Hospital: Vanderbilt University School of Nursing/Norwalk Community Health Center, Inc. (NCHC)/NCHC at Smilow Life Center

Name of participant: _____ Age: _____

The following information is provided to inform you about the research project and your participation in it. Please read this form carefully and feel free to ask any questions you may have about this study and the information given below. You will be given an opportunity to ask questions, and your questions will be answered. You will be offered the opportunity to be given a signed copy of this consent form.

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.

Your consent is being sought to participate in a month-long research study because you take medication regularly for a chronic illness and you own and use a mobile smartphone. The purpose of this research is to understand if using the Medisafe app in comparison to using a printed-out list of your medications affects how well you take your medications, your perspectives and knowledge of your medications, and the support you receive to take your medications. We will also ask for feedback on the use of the app or printed-out medication list. Your participation is voluntary, and you may stop being in this study at any time. You may also choose not to be in this study and get other treatments without changing your healthcare, services or other rights. 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 or not you still want to be in this study.

If you consent to take part in the study, you will complete a survey at the beginning of and at the end of the study (one month from the start date). Each survey will take approximately 15 minutes and will include questions about yourself, how you take your medications, your perspectives on and support you receive for taking your medications. You will enter your medications into the app. If you need help with this, the researcher can help you with this. We will also ask you for a medication list. You will need to obtain a copy of your medications from your providers. After completing the survey, you will be randomized to either an **(a) intervention group** where you will use a free app, called Medisafe, to manage your medications for one month, including receiving daily reminders to take your medications or a **(b) wait-list control group** where you will receive a printed-out medication list to take home with you. At the end of the study, you will have the option to meet with the Principal Investigator (PI) to set up the Medisafe app for future use.

Taking part in this study may be an inconvenience to you as it will require you to spend time completing the surveys and/or using the app. Potential risks of participating in the study include that you input your medication information incorrectly into the app, you might receive incorrect reminders, or the app does not function properly. Another risk is also a breach of confidentiality. However, we have taken steps to mitigate this risk as best as possible. Participation in the study might benefit you as you may find the app or the printed-out medication list helpful in taking your medications.

Alternative medication management apps that offer similar features as the Medisafe app might be available to you for use. The alternative is for you not to participate in the study and continue taking your medications as you have been. The PI is a PhD student at Vanderbilt University School of Nursing and is working with the Norwalk Community Health Center (NCHC)/NCHC's Smilow Life Center location to complete this study.

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

You are being asked to participate in a research study because over the course of one month, we would like to learn if the use of an app that lists your medications helps you take your medications, affects your

knowledge about your medications and/or affects any support you receive to take your medications. Your perspectives are vital to our understanding how the use of an app might help patients better manage their medications.

Procedures to be followed and approximate duration of the study:

If you consent to participate, you will receive a printed-out copy of your current medication list in the electronic medical record from clinic staff. The PI will ask for this copy from you to help you put the information into the app. If you are randomly selected for the **intervention group**, the PI will provide you with a link to download a free publicly available app called Medisafe and using the printed-out medication list, the PI will help you input the medications into the app. The PI will also show you different features of the app. Once the app is set up, during the month-long study, you will receive a daily medication reminder on your mobile phone to alert you to take your medication and you will have the opportunity to open the app and indicate that you want to take, skip or reschedule taking the medication. You can use the app to also obtain information on the medications you are taking and to access a social support feature termed a Medfriend. The Medfriend feature allows you to invite someone you know to help you take your medications correctly. At the end of the study, you will complete another survey. At this time, Medisafe will provide the PI with de-identified data on your app usage during the study, but they will never know your identity. If you are in the **wait-list control group,** the PI will provide you with a hard copy of your current medication list to take home with you. At the end of the study, you will have the option to meet with the PI to help you set up the Medisafe app for use.

Expected costs:

There are no expected costs to you for participating in this study.

Description of the discomforts, inconveniences, and/or risks that can be reasonably expected as a result of participation in this study:

The inconveniences as a result of participating are the time it takes you to take the surveys and set up and use the app, as well as travel to and from the health center. A risk of participating in the study may be a breach of confidentiality but steps will be taken to lessen this risk. Another risk of this study may be that you input the medication information incorrectly or you receive an incorrect reminder, or the app does not function properly. However, steps will be taken to ensure the correct medication information will be put into the app.

Good effects that might result from this study:

a) The benefits to science and humankind that <u>might</u> result from this study. The benefits that might result are that more information regarding the benefits of using a medication adherence mobile phone application will become known.

b) The benefits you might get from being in this study. You may find that using the app or medication list helps you to take your medications properly. This may help you to become healthier. The app will be available to you to use after the study is completed if you choose to do so. It is also possible that you may not benefit directly from participating in this study.

Study Results:

The results of the study will not be shared with you unless you request to know. However, if you wish to learn the results of the study, the information will be shared with you.

Compensation for participation:

Once you consent to participating, complete the baseline questionnaire and download and set up the app or review your printed-out medication list, you will receive a $25.00 gift card. After either using the app for

one month or being in the wait-list control group and filling out the follow-up questionnaire, you will receive an additional $35.00 gift card.

Circumstances under which the Principal Investigator may withdraw you from study participation:

If you express discomfort about being in the research study, the PI may withdraw you from the research study.

What happens if you choose to withdraw from study participation?

Any information you provide prior to your decision to withdraw will be destroyed and will not be used as part of the analysis.

Contact Information.

If you should have any questions about this research study or possibly injury, please feel free to contact Christa Hartch, RN at (203) 900-7942 or my Faculty Advisor**,** Deonni Stolldorf, RN, PhD at (615) 343-0637.

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.

Confidentiality:

All efforts, within reason, will be made to keep your personal information in your research record confidential but total confidentiality cannot be guaranteed. We will maintain all survey responses and any contact information you provide confidential and in a secure password protected study database. A Study ID will be assigned to your data and all personal identifiers will be removed from the data once the data is downloaded for analysis. The file linking your personal information with the Study ID will be stored separate from the data on a password protected computer in a password protected file. Any hard copies of data and survey information provided will be de-identified and stored in a secure, locked file cabinet at the NCHC/NCHC's Smilow Life Center location only accessible to the PI. At no point will your information be associated with the data during publications or presentations. These steps lessen the risk of a breach of confidentiality. The app company, Medisafe, will be blinded to your identification. The PI will maintain a master table linking your URL with your Study ID and your respective Electronic Medical Record (EMR) number. The PI will be the only person with access to this table and it will be stored separate from your data on a password-protected Excel file on a password protected computer only accessible by the PI. Medisafe will use secure methods to provide the PI with a report of the usage data for the individual URL after the study is finished. The app is HIPAA compliant. Following consent, printed-out copies of your medication list from your Electronic Medical Record (EMR) at NCHC/NCHC's Smilow Life Center location will be provided to you. Once you confirm your name and date of birth and the medications are put into the app, all identifying information on the printed-out copy will be blackened out and replaced with a Study ID. Any hard copy (paper) study documents with patient identification information on them such as consent forms and/or filled out flyer or referral forms will be stored in a locked file cabinet at the NCHC/NCHC at Smilow Life Center whose key is only available to the PI. After study completion of the study, scanned copies of these documents will be housed in a secure file repository in the REDCap database. Excel tables of patients who are screened and/or enrolled in the study will also be maintained in a password-protected Excel file to which only the PI has access. No patient identifying information will be transferred from the NCHC/NCHC's Smilow Life Center location to Vanderbilt University or Medisafe.

This study may have some support from the National Institutes of Health (NIH). If so, 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.

Clinical Trials Registry:

A description of this clinical trial will be available on: https://nam04.safelinks.protection.outlook.com/?url=http%3A%2F%2Fwww.clinicaltrials.gov%2F&data=04%7C01%7Cchrista.e.hartch%40vanderbilt.edu%7Cc6c5575be83d492ae09d08d9931967f4%7Cba5a7f39e3be4ab3b45067fa80faecad%7C0%7C0%7C637702559594496066%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C1000&sdata=PU7F%2BI4%2BOceDo5visajqBf7ydzhoD%2BKA1vvTi5qGbas%3D&reserved=0 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.

STATEMENT BY PERSON AGREEING TO PARTICIPATE IN THIS STUDY

I have read this informed consent document and the material contained in it has been explained to me. All my questions have been answered, and I freely and voluntarily choose to participate.

Date	Signature of patient/volunteer

Consent obtained by:

Date	Signature
	Printed Name and Title