CONSENT TO BE PART OF A RESEARCH STUDY FOR ADULTS AND CAREGIVERS OF ADULT PERSONS WITH COGNITIVE IMPAIRMENT

Sponsor / Study Title:	**MapHabit, Inc. / Umbrella Study to Evaluate the Feasibility of Collecting User Interaction Data in Participants Using MapHabit Software**
Protocol Number:	**MH001**
Principal Investigator: (Study Doctor)	**«PiFullName»**
Telephone:	**«IcfPhoneNumber»**
Address:	**«PiLocations»**

This form is for use in a research study that may involve subjects who may or may not have the capacity to consent to take part in the study. When the subject cannot legally consent to take part, pronouns "you" and "your" should be read as referring to the subject rather than the person (legally authorized representative) who is signing this form for the subject. In cases where the subject's representative gives consent, the subject should be informed about the study to the extent possible given his/her understanding. During the course of the study, if the subject regains the capacity to consent, informed consent will be obtained from the subject and the subject offered the ability to leave the study if desired.

This informed consent form is for caregivers of individuals with Alzheimer's Disease or Alzheimer's Disease Related Dementias (AD/ADRD) interested in giving feedback on their views on independence for their loved one with AD/ADRD and for themselves as a caregiver.

In order to be eligible for this study as a caregiver, one must meet the following criteria:

- Reside in the United States
- Be at or above the age of majority (18)
- Be the primary caregiver of an individual with cognitive impairment such as AD/ADRD
- Be able to speak and write in English

This consent form gives you important information about a research study. A research study helps scientists and clinicians learn new information to improve medical practice and patient care.

This informed consent form is also for persons living with Alzheimer's Disease or Alzheimer's Disease Related Dementias (PLwAD/ADRD) interested in engaging in the MapHabit app with their caregiver.

In order to be eligible for this study as a PLwAD/ADRD, one must meet the following criteria:

- Reside in the United States
- Be at or above the age of majority (18)
- Living with cognitive impairment such as AD/ADRD

This consent form gives you important information about a research study. A research study helps scientists and clinicians learn new information to improve medical practice and patient care.

Please read this consent form carefully and take your time making a decision. The first section gives you an overview of the key information you should know about the research study. More detailed information about these topics may be found in the pages that follow.

The form may contain words that you do not understand. Please ask questions about anything you do not understand. We encourage you to talk to others (for example, your friends, family, or your doctor) before you decide to participate in this research study.

KEY INFORMATION
THINGS YOU SHOULD KNOW:

- We are asking you to participate in this research study because you are acting as a caregiver for a person living with dementia or are an individual with cognitive impairment such as AD/ADRD.
- Participation in this research study is voluntary. You may choose not to participate in this research study or may choose to leave the research study at any time.
- The purpose of this study is to find out if providing personalized dementia caregiver education via the MapHabit software can improve caregiver wellbeing, reduce stress, increase confidence to provide care, and improve independence of the person living with dementia.
- If you choose to participate, you will be asked to use the MapHabit software OR similar cognitive engagement as part of your daily routine for up to six-months. It is expected that this daily usage can range from 15 – 30 minutes per day, totaling to approximately 2 hours per week.
- You will be contacted/notified by the research lead regarding details of your participation following the completion of this consent form and subsequent baseline assessment.
- If you are not the Next-of-Kin/Legally Authorized Representative (LAR) of the individual that you care for, the Next-of-Kin/LAR will also need to provide consent on behalf of the subject with cognitive impairment.
- You will be given an electronic tablet (often called a smart device) that is pre-loaded with the study apps and/or the MapHabit System. You will only be able to use this device for the purposes of the research study.

- A trained member of our research team will be able to assist with trouble shooting on the device.
- The primary caregiver, will be asked to complete a 60-minute guided online survey about the study subject for whom you act as a primary caregiver at the start of this research study AND at the middle of this research study AND at the end of this research study. You will be able to access these assessments securely online with the support of a research team member.
- The individual with cognitive impairment will NOT participate in any study related assessments
- The MapHabit System is HIPAA compliant. However, transmission of information via the internet is not completely secure, so there is a small risk of unintentional release of your information and safeguards are in place to protect your personal information.
- On-going support from the MapHabit research and education staff, led by the research team will be provided to you throughout the study and will occur on a scheduled basis.
- There are no known physical risks or discomfort from participating in this study. However, transmission of information via the internet is not completely secure. There is a small risk of unintentional release of your information. However, safeguards are in place to protect your personal information.
- There may be no direct benefit to you from participating in this study other than experiencing the potential positive outcomes that may come about from utilizing the MapHabit System of improved quality of life and bolstered independence. This study will help scientists and clinicians learn more about cognitive impairments including Alzheimer's disease, other forms of dementia, and Down Syndrome and it is hoped that this information will help in the care of other people.
- If you decide not to participate in this research, you will continue to get all the care you currently receive. In this case you would not be eligible to use the MapHabit software.

INTRODUCTION

It is important that you read and understand the following explanation of the proposed research study before you agree to participate. The contents of this consent form include:

- Key Information
- Introduction
- Relevance
- Purpose of the study
- Description of the study
- Expectations
- Benefits
- Risks and/or Discomforts
- Compensation and Costs
- New Information
- Confidentiality and use of research results
- Withdrawal
- Contact
- Research subject rights
- Consent

RELEVANCE

We are seeking to gain insight into the usability, acceptability, feasibility and effectiveness of a personalized dementia caregiver education via the MapHabit software. We want to gain a deeper understanding of how personalized education platform can improve caregiver wellbeing, reduce stress, increase confidence to provide care and improve independence of the person living with dementia. We expect this information will assist researchers to better understand and develop educational resources, and technological solutions.

PURPOSE OF THE STUDY

The purpose of this study is to investigate the usability, acceptability, feasibility and effectiveness of a personalized dementia caregiver education administered via the MapHabit software. Additionally, the study will assess if providing personalized dementia caregiver education via the MapHabit software can improve caregiver wellbeing, reduce stress, increase confidence to provide care and improve independence of the person living with dementia.

Interaction data can be used for refining the software and educational training components during subsequent revisions and may be analyzed for future clinical research. You are being asked to participate in this research study as part of your engagement with the MapHabit software and the caregiver training program. The study will be a randomized controlled clinical trial, in which two conditions will be investigated: 1) control condition in which the MapHabit program alone is incorporated in the participant's daily care and 2) experimental condition in which the MapHabit Program plus the new care partner training program is implemented into the daily care received by participants. The study duration will be a 6-month intervention. Your participation is completely voluntary. You may leave the study at any time.

About 50 caregiver/subject dyads will participate in this study. 25 in each condition.

PURPOSE OF THE SURVEYS

We are seeking the participation of the caregivers of individuals with AD/ADRD to better understand the needs of caregivers to provide quality care, reduce caregiver stress, improve caregiver confidence, and improve independence of the person living with dementia. The ADCS-ADL assessment assesses the completion of activities of daily living for persons living with dementia or cognitive impairment throughout the study. The Caregiver Confidence in Sign/Symptom Management (CCSM) survey assess caregiver confidence in sign/symptom management and to determine caregiver needs and outcomes of the caregiver training program. The Caregiver Well-Being Scale (CWBS) identifies areas of caregiver strength and areas in which additional support is needed. The Zarit Scale of Caregiver Burden assesses caregiver stress and burden due to care provided. The MapHabit Net-Promoter Scale surveys subjects on their experience with the MapHabit platform.

DESCRIPTION OF STUDY

The following information describes what will happen while you participate in the study. If you wish to do this study, you will sign and date this consent.

The research team will determine if you are eligible to participate in the study.

An eligibility check will be conducted during a scheduled video call meeting with the principal investigator or trained research team. If you are determined to be eligible for participating in this study, you will be asked to review this Research Consent Form. If you wish to participate in this study, you will be asked to sign and date this Research Consent Form. If you are determined to be ineligible for any cause, or do not wish to participate in this study, your participation will end at this point and no further contact regarding this study will be made.

After you sign and date this Research Consent Form:

You will be randomly assigned to a study group. You will be assigned a unique Participant ID that is associated with your data and the MapHabit software will begin recording interactions between you and the software user interface. Recording occurs automatically. No additional input is required from you, other than routine use of the MapHabit system as intended.

The following information will be collected automatically:

1. Duration of time which each screen or prompt was displayed to you
2. Actions (for example, tapping, swiping, typing) you perform by interacting with elements of the software interface (for example, buttons, dialog box)
3. Application logs, such as error reports, unexpected shutdowns, etc.
4. Data regarding interactions between the MapHabit software and connected applications not developed by MapHabit, Inc. This may include, but is not limited to, commands passed to the MapHabit software from voice-assisted technologies such as Amazon Alexa; and biometric data passed to the MapHabit software from wearable technologies such as Apple iWatch.

x

Study Activity	Enrollment (Day 0)	Continuously	End of Participation
Inclusion/Exclusion screening	X		
Subject completes enrollment to this study within the MapHabit software via virtual onboarding process	X		
Subject is evaluated for ability to provide Informed Consent	X		
Informed Consent is provided by Subject	X		
Assignment of study group	X		
Assignment of unique subject number	X		
Subject completes virtual baseline survey/assessment	X		
Subject is provided Getting Started Package with Tablet, Instructions, and Technology Accessories		X	
Meet via video call with MapHabit Support Coach to receive education orientation and support throughout the study		X	
In-app data collection		X	
Subject completes virtual study midpoint survey/assessment	X		
Subject in caregiver education program for 6-months		X	
Subject completes virtual exit survey/assessment			X
Optional individual in-depth qualitative interview			X

Study Activity	Enrollment (Day 0)	Continuously	End of Participation
Inclusion/Exclusion screening	X		
Subject completes enrollment to this study within the MapHabit software via virtual onboarding process	X		
Subject is evaluated for ability to provide Informed Consent	X		
Informed Consent is provided by Subject	X		
Assignment of study group	X		
Study Completion, Compensation provided, all equipment must be returned (if applicable)			X

After Study Treatment
Your participation in this research study is 6-months. When you complete the study at the end of 6-months you will be compensated with a $200 gift card, Your iPad will be unlocked and provided to you to keep and use in appreciation for your having participated and completed in the study, and a 1-year subscription to the MapHabit platform. If assigned to the control group, you will be provided a fully unlocked version of the care partner education course. Your participation in this study will end and we will cease to collect user interaction data.

EXPECTATIONS
If you participate in this study, you will be expected to routinely participate in the caregiver training program via the MapHabit software as intended for 6-months.

ALTERNATIVES TO PARTICIPATION
This research study is for research purposes only. The only alternative is to not participate in this study.

BENEFITS
There may be a direct benefit to you from participating in this study. The caregiver training program provides education about how to care for your family member with cognitive impairment or AD/ADRD. However, due to the study being a feasibility study there may also be no direct benefit to you from participating in this study. Additional benefits to you or others may arise by improving the MapHabit software, and by refining the ability to improve the quality of

life and wellbeing of caregivers and recipients of caregiving. Knowledge gained from this study may benefit others and society in the future. This may benefit society by improving care for those diagnosed with Alzheimer's Disease, Alzheimer's Disease Related Dementias, Mild Cognitive Impairment, Traumatic Brain Injury, Down Syndrome or other forms of cognitive impairment.

RISKS AND/OR DISCOMFORTS

There are no known potential risks and/or discomforts associated with the passive collection of user interaction measures through software. Additionally, there are no known risks to providing evidence informed caregiver education.

Users are not identifiable from this information. Data from the app is not monitored in real time. MapHabit does not collect data about health status. If there is a change in health status, please notify the principle investigator or clinical research team at the site of research (MapHabit Inc).

In order to use the caregiver training program on the MapHabit software you will be asked to agree to the Terms of Use and Privacy Policy. While using the software, data about you including personal health information, location, other communication data, and internet usage within the MapHabit app will be collected and transmitted to the researchers AND/OR to people outside of the research study. A complete description of this data collection and sharing is found in the Privacy Policy. The MapHabit System is HIPPA compliant. However, transmission of information via the internet is not completely secure, so there is a small risk of unintentional release of your information and safeguards are in place to protect your personal information. The Privacy Policy provides instructions on how to request deletion of your personal data if you decide to do that in the future. While the Terms of Use may include statements limiting your rights if you are harmed in this study, you do not release the investigator, sponsor, institution, or agents from responsibility for mistakes, and these statements do not apply to the use of the software in this research study. If you decide you do not want to agree, then you can decide not to participate in the study.

You will be emailed a PDF copy of this signed and dated consent form. There may be risks of loss of privacy and confidentiality if the PDF copy of this consent form is viewed and/or stored on a personal electronic device (PED), especially if that PED is shared with other users or is lost, hacked, or subject to a search warrant or subpoena. Also, the PDF copy of the consent may not be able to be permanently removed from a PED.

Because this is a research study, there may be additional risks that we cannot predict right now.

CONFIDENTIALITY AND USE OF RESEARCH RESULTS

The results of this study may be published or presented, but your identity and records will not be revealed unless required by Federal Law. A Federal Law allows the U.S. Food and Drug Administration, Office for Human Research Protections, Government Accountability Office and other Federal agencies, the Research and Development Committee, the Institutional Review Board (IRB), and the Human Studies Subcommittee to review records.

Information (for example, your Participant ID number, your user-software interaction data) collected by the MapHabit software will be transmitted by encrypted communication to MapHabit, Inc. Your personal identifying information (such as your name) is protected in accordance with the Health Insurance Portability and Accountability Act (HIPAA).

Any information that can identify you will remain confidential. This information will be kept for a duration of 10 years, the minimum duration in accordance with Georgia state law. After this time, your information will be destroyed or de-identified If your information is de-identified, we will replace all identifying information with a code that does not directly identify you.

Your participation in this study is confidential. You will not be identified in any publication from this study or in any data files shared with other researchers. The information in this study will only be used publicly in ways that will not reveal who you are. Other researchers may request access to de-identified data in the future. Data can only be shared without identifiers, preserving the confidentiality of the information and when approved by the original research team.

If you withdraw from this study, all data collected until the time of withdraw can be used for this research study as described above. After you have withdrawn from this study, no additional user interaction data will be collected from you.

FUTURE PUBLICATION
Statistical analyses of all data will be carried out independently of investigators by a biostatistical resource department of an academic health center for validation.

This project will be published. Documentation of the project will be shared internally and in a publication journal.

COMPENSATION
Compensation will be provided for the Caregivers who participate in this research study. It will be granted based on competing study milestones as described below.

- $20 for initial enrollment (enrollment is defined as being onboarded into the MapHabit app and completing baseline assessments)
- $80 for using MapHabit for 4 months and completing mid-point study assessments
- $100 for completing the study and endline assessments at 6-months
- Study iPad will be yours to keep for completing the study and endline assessments at 6-months
- A 1-year MapHabit Software subscription for completing the study and endline assessments at 6-months at no charge.

COSTS TO YOU FOR PARTICIPATING IN THIS RESEARCH STUDY
There is no cost to you for taking part in this study. All study costs incurred by collecting user interaction information will be paid for by MapHabit, Inc.

COMPENSATION AND MEDICAL CARE FOR ANY INJURIES RESULTING FROM STUDY PARTICIPATION

If you are injured from this research study, treatment will be available, including first aid, emergency treatment and follow-up care, as needed, by your regular medical and behavioral care providers. MapHabit, Inc. does not pay for any medical care for injury or illness related to your participation in this research study. If you receive any type of medical care, that you believe resulted from an illness or injury related to this study, you must contact the principal investigator immediately.

You will not lose any of your legal rights or release the sponsor, study investigator, research team, or study site from liability for mistakes by signing and dating this consent document.

Non-emergency injuries resulting from your participation in this study should be reported immediately to the research coordinator using the contact information on page 1 of this consent form.

NEW INFORMATION

You will be given all new significant information that may be discovered during the course of this study that can influence your willingness to continue the study.

PARTICIPATION AND WITHDRAWAL

Your decision to participate in this study is voluntary. You may choose not to participate, or you may withdraw from this study for any reason without penalty or loss of benefits to which you are otherwise entitled and without any effect on your future medical care. Any information collected up to the point of your withdrawal cannot be removed from this study. You can withdraw from this study by notifying the principle investigator OR research coordinators in person, or in writing by e-mail to research@maphabit.com.

Your participation in this study may be terminated before the completion of the study period for, but not limited to, the following reasons:

- The study is terminated early
- Incomplete adherence to study instructions i.e., exceeding time span to complete education modules)
- You withdraw your consent to participate in this study
- Other, unforeseen reasons

WHOM TO CONTACT ABOUT THIS STUDY

During your participation in this study, if you experience any medical problems, experience a research-related injury, or have questions, concerns or complaints regarding this study, please contact the study investigator and/or clinical coordinator at the telephone number listed on page 1 of this document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact:

- By mail:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00039611.

You can report the technical issues occurring during use of the software via e-mail address to research@maphabit.com.

RESEARCH SUBJECTS RIGHTS

I have read all of the above. If necessary, because I had additional questions, I have contacted the research team and they have explained the study to me and answered all of my questions. I have been told of the risks and benefits of this study. I understand that I am not required to participate in this study, and my refusal to participate will involve no penalty or loss of rights to which I am entitled. I may withdraw from this study at any time without penalty or loss of other benefits to which I am entitled.

The results of this study may be published. My identity and records will not be revealed unless required by law.

I have been informed that because this study involves articles regulated by the FDA (Food and Drug Administration), the FDA may choose to inspect research identifying me as a subject in the course of their investigation.

In case there are **non-emergency** medical problems or questions, concerns, or complaints, I have been advised to contact the research team (Research@maphabit.com) during business hours (Monday through Friday 9:00AM - 5:00PM EST).

May we keep your information on file and contact you regarding any new research studies that may occur in the future?

❑ _____ (initials) Yes
❑ _____ (initials) No

My electronic signature below certifies that I have read the above description of this research study. I understand the risks and benefits involved, and all my questions have been answered to my satisfaction. Furthermore, I understand that any future questions I may have will also be answered by a member of the research team. I voluntarily agree to take part in this study. I understand that I will receive a copy of this consent form.

_____ _____

Name of Caregiver (Printed) Relationship of Caregiver to Person Living with Dementia

_____

Name of Person Living with Dementia (Printed)

_____ _____

Signature of Caregiver Date Time

_____ _____

Signature of Person Living with Dementia Date Time

_____

Name of Legally Authorized Representative (if applicable)

_____

Relationship of Legally Authorized Representative (if applicable)

_____ _____

Signature of Legally Authorized Representative Date Time

_____

Name of personnel conducting Informed Consent discussion

_____ _____

Signature of personnel conducting Informed Consent discussion Date Time