CEDARS-SINAI MEDICAL CENTER®

CONSENT FORM FOR RESEARCH

Title: Behavioral Economics to Improve Antihypertensive Therapy Adherence (BETA)

STUDY SUPPORT PROVIDED BY: SMIDT HEART INSTITUTE

PRINCIPAL INVESTIGATOR:
DR. JOSEPH EBINGER, MD, MS

STUDY CONTACT PHONE NUMBER AT CSMC: (424) 315-2246

AFTER HOURS CONTACT (24 HOURS): (310) 423-2726

KEY INFORMATION ABOUT THIS RESEARCH STUDY

We are seeking your consent to take part in this research study. Your participation in this research is voluntary. If you choose to participate, you can stop at any time. Please consider the following summary, along with the more detailed information provided throughout this consent form.

- The purpose of this study is to identify tools to help participants take their anti- hypertension medication on time.
- There are two different methods for collecting data. The first method includes a device that requires on-site attendance for each visit. The second method includes a device that allows for remote audio or video recordings for each visit. You will be selected to participate in one or the other.
- The main procedures of the on-site method include receiving daily text message reminders for 3 months and a prize drawing during clinic visits, depending on the group to which you are randomly assigned. You will also receive a MEMS-cap device to take home, which collects data related to pill-taking, as well as instructions for use. If you choose to participate you will be asked to return to the clinic once per month for 3 months, and then during each regular clinic visit, until 9 months after your enrollment into the study, for a total of at least 5 visits. The final study visit will be scheduled at the end of 9 months from the day you enroll in the study.
  The main procedures of the remote method include receiving daily text message reminders for 3 months and a prize drawing during remote follow up visits. The non-randomized remote trial uses a medication adherence device called Wisepill. Remote data collection and monitoring will occur virtually once per month for 3 months with weekly blood pressure readings using a Withings blood pressure device.
- All research studies involve some risks. Risks or discomforts from this study may include learning to use a new pill bottle for managing your medications and presenting to clinic once a month for 3 months.

- The possible benefits of taking part in this study are achieving a more consistent routine for taking your anti-hypertension medication.

- If you choose not to participate, there may be other choices available to you. Some other choices may include continuing your care without receiving text messages or prize drawings. You will not lose any services, benefits or rights you would normally have if you choose not to participate. Please discuss your choices with the researchers.

Please take time to read this entire form and ask questions before deciding whether to participate in this study. You are encouraged to talk with family members, friends, and/or healthcare providers before you make your decision.

1. WHAT IS THE PURPOSE OF THIS RESEARCH STUDY?

We are doing this study to see if daily text message reminders and prize incentives during clinic visits are associated with more consistent medication use than without reminders and incentives. We want to know if these reminders and incentives may be helpful to patients in reducing the amount of times they may forget to take their anti-hypertension medication, and thus increasing their control of their blood pressure.

You are being asked to take part in this research study because you have high blood pressure.

The study will enroll up to 65 people in total.

2. WHAT WILL HAPPEN DURING THE STUDY?

This section provides a general overview of what will happen during your participation in this study. Information included below should be considered along with the flowchart of procedures attached as an Appendix.

The flowchart shows a timeline for research-related or standard of care procedures that are involved in your participation in this study. **Research-related procedures** are those performed solely for the research. They would not be performed if you did not take part in the study. **Standard of care (routine)** procedures would be performed both as part of this study and if you do not participate in this study.

A table describing common medical procedures done solely for the purposes of monitoring and assessing your condition during this study is attached as an Appendix at the end of this consent form. Standard of care procedures that will be repeated or done at greater frequency are listed in the flow chart Appendix.

Overview of study:

On-Site Visits: MEMS Device

The on-site MEMS method includes a randomized controlled trial. It is designed to test the feasibility, acceptability, and efficacy of using daily text message reminders and prize incentives to increase adherence to hypertension medication.

"**Randomized**" means that there is a formal process for randomly allocating patients to one of the study groups. By consenting to participate, you will be randomly allocated to one of these groups.

This study has 3 study groups:

- A group of 20 individuals who will receive daily text message reminders for 3 months ("Message" group). These individuals will receive a MEMS-cap device for data collection for a period of 9 months.
- A group of 20 individuals who will receive daily text message reminders for 3 months and will also be eligible for prize drawings during the first 3 clinic visits ("Incentive" group). These individuals will receive a MEMS-cap device for data collection for a period of 9 months.
- A group of 20 individuals who will receive care as usual (i.e. no text messages or prize drawings). These individuals ("Control" group) will receive a MEMS-cap device for data collection for a period of 9 months.

If you are randomized to one of the groups receiving daily text message reminders, your phone number will be shared with Twilio, Inc. If you have a phone plan that includes charges for receipt of text messages, this may result in additional charges on your phone plan.

All patients will be followed over a 9-month period regardless of study group. Patients will be asked to return to the clinic for monthly visits for the first 3 months, then during each scheduled clinic visit. The final study visit will take place at the end of 9 months after their enrollment, resulting in a total of at least 5 study visits. During each visit, study staff will collect information on medication-taking routines. If the patients report that their current medication routine is not working, their physician will work with them to identify a new routine. Patients will also be asked to fill out a brief (<30 minutes) survey to collect other data of interest.

Remote Visits: Wisepill Device

The remote Wisepill method will not be randomized, all participants will be enrolled in the incentive group. Patients enrolled in the completely remote adherence trial will be followed over a 3 month period. Patients will receive the Wisepill device and the Withings blood pressure device at the baseline visit. Remote monitoring and data collection will occur virtually at 1 month, 2 months, and 3 months along with weekly blood pressure readings.

Each of these different approaches could help your condition but could also cause side effects. This study will allow the researchers to learn whether the different approaches are better, the same, or worse than the current standard of care. The use of text message reminders and prize incentives are considered safe; however, they are not part of the current standard of care.

How long will you be in the study?
Those enrolled using the on-site MEMS method will be in this study for approximately 9 months. The total time includes clinic visits every month for the first 3 months, and then during each regular clinic visit until month 9. During the last month, we will schedule a final study visit.

Those enrolled using the remote Wisepill method will be in the study for approximately 3 months.

Optional Sub-study
There is also an optional sub-study described later in this consent form. You are not required to

take part in the sub-study. You can say no to the sub-study and still be in the main study.

3. WHAT ARE THE POSSIBLE RISKS?

Risks of common medical procedures performed solely for research purposes are described in a table attached to the end of this consent form as an Appendix. Side effects and risks of standard of care procedures are not described in this consent form.

This section describes the possible risks and/or discomforts we anticipate you could experience that are related to the study procedures

Using a new pill bottle to monitor medication use involves changes to current habits for many patients. Risk is considered minimal, however, learning a new task can be uncomfortable to some participants.

4. ARE THERE BENEFITS IN TAKING PART IN THE STUDY?

If you agree to take part in this research study, there may or may not be direct medical benefit to you. The possible benefits of taking part in the research study are improved medication adherence and greater control of hypertension. However, no benefit is guaranteed. It is possible that your condition may remain unchanged or even get worse.

We hope the information learned from this research study will benefit other individuals with hypertension in the future by helping us to learn how best to help patients adhere to their medication schedule.

5. WHY WOULD MY PARTICIPATION BE STOPPED?

Your participation in this study may be stopped at any time by the researcher or the sponsor without your consent for any reason, including if:

- The study is stopped or suspended;
- Funding for the study is reduced, stopped or withdrawn;
- It is in your best interest;
- You do not consent to continue in the study after being told of changes in the research that may affect you;
- You do not follow the study procedures.

6. ARE THERE ANY OTHER OPTIONS?

Your participation is voluntary, so you have the right to decline to participate or to withdraw from this research study at any time without any penalty or loss of benefits to which you would be entitled outside of the study. Choosing not to participate will not affect the care you receive at Cedars-Sinai Health System.

If you decide not to take part in this study, you have other choices. For example:

- you may choose to be treated following the usual clinical approach.

- you may choose to take part in a different study at CSMC or elsewhere, if one is available
- you could decide not to be treated.

The researcher will discuss these options and their risks and benefits with you.

7. WILL MY INFORMATION BE KEPT CONFIDENTIAL?

We will do our best to make sure that the personal information collected as part of this study is kept private. However, we cannot guarantee total privacy. A copy of your research consent and authorization forms may be filed in your electronic medical record at CSMC. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other identifiable personal information will not be used. Organizations that may look at and/or copy your medical records for research oversight, quality assurance, and data analysis include: accrediting agencies, government and regulatory groups (such as Food and Drug Administration (FDA), Office for Human Research Protections (OHRP), etc.), safety monitors, companies that sponsor the study, and authorized representatives of the sponsor.

Attached to this consent form is an "Authorization Form" that outlines with whom your information may be shared for the purposes of this research and under what circumstances.

We might share your information and/or research samples collected in this study with other researchers at Cedars-Sinai, other academic institutions, or third-party commercial entities for future research without additional informed consent from you. Information that identifies you will be removed and will not be shared with other researchers or anyone outside of Cedars-Sinai.

All consented participants (must be fully signed consents) will have the option to obtain repeat blood pressure monitoring. Results from these testing may be shared with the participant and or referring cardiologist.

8. WHAT IF I BECOME ILL OR INJURED BECAUSE OF TAKING PART IN THIS STUDY?

You will not be in danger of any illness or injury from this research study. However, should you believe that you are ill or have been injured as a result of your participation, please contact the study team at the phone number listed on page 1 of this consent form.

As noted under the Overview of the Study, any decisions to begin or change treatment for your hypertension will be based on current clinical guidelines and will be approved by your clinical cardiologist. It is not anticipated that your participation in this study should affect the risks associated with the clinical management of hypertension.

9. FINANCIAL CONSIDERATIONS

Please review the attached flowchart for a listing of items, drugs and services that will be billed to you and/or your insurance and those that will be covered by the study sponsor.

Standard of care procedures and related items, drugs and procedures will be charged to you or your insurance company. You remain responsible for all deductibles, co-pays, and balances under your health benefit plan.

The Researcher and/or research staff will seek pre-authorization from your insurance company for any order labs tests and medications. Before any study procedures are performed, pre-authorization must be received from your insurance company. If your insurance company denies coverage, you may decline to participate in the Study or you may choose to pay out of pocket. You should check with your health benefit plan if you have questions or concerns about your insurance coverage.

Compensation for Participating

Those enrolled using the on-site MEMs method will be paid $50 after completion of each of the following research visits: baseline, 3 month, and 9 month. If you complete all visits, you will receive an additional $50 at the end of the study. Those enrolled using the remote Wisepill protocol will receive $50 at baseline and $50 at 3 month. You will only be paid for those visits you complete. Parking validation may be provided for each visit.

The researchers are conducting an incentive drawing (for participants in the Incentives group) with the chance to win $0, $25, $50. You have about a 1 in 3 chance of winning the Drawing. No individual is guaranteed to win any prize. All Drawing entries have an equal chance of winning. There is one way to enter the Drawing.

Research Participant Entry: You will be automatically entered into the Drawing if you are randomized into the incentives group and report greater than 80% compliance to medication adherence.
The winner of the Drawing will be randomly selected once every month for the first three months of participation. If you win, you will be contacted by the Beta research team via either phone r email.

You may have to fill out a W-9 form to get paid. Our accounting department at Cedars-Sinai will keep the W-9 form. Any amount of payment may be reportable to the IRS. If you receive $600 or more from Cedars-Sinai in a calendar year, a 1099 form will be filed with the IRS in accordance with federal tax law. Check with a tax professional if you have questions.

Payment will be managed by an outside company. They will give you a debit card. Your payment for taking part in the research will be loaded onto the card. The money will generally be available within 4weeks after you finish each study visit. You will need to share your name, address, Social Security number and birthdate with the outside company to get this debit card. Your information will be stored in a protected fashion. Your information will be removed from the debit card system once the study is finished and the money on the card has been used. The outside company will not share your information with any other third parties.

Financial Interest in the Research

The PI and institution have no potential financial conflict of interest with respect to this study.

10. WHAT IF I HAVE QUESTIONS OR PROBLEMS?

Please contact one of the investigators listed on the first page of this form for questions or concerns about the research.

If you have questions, problems, or concerns that you want to discuss with someone who is not associated with this study, or want to offer suggestions or feedback, please contact:

Cedars-Sinai Human Research Protection Program (HRPP) Phone: (310) 423-3783
Email: ResearchConcerns@cshs.org

The Cedars-Sinai HRPP has been established to protect the rights and welfare of research participants. You may also contact the Cedars-Sinai HRPP if you want to offer input or obtain information regarding the study.

11. CONSENT PROVISIONS

If you sign this form below, it means that:

(1) You have taken the time to carefully read and understand the information presented in this informed consent form; you should discuss it with others, and if appropriate seek a second opinion to make an informed decision;
(2) The information concerning the research study and its involved procedures has been fully explained to you and your questions have been answered to your satisfaction;
(3) You have received and understand all of the information you desire regarding your participation in the research study;
(4) You have considered the potential risks, any anticipated benefits and alternatives (and their relative risks and benefits) of participation;
(5) You are voluntarily agreeing to participate in this research study;
(6) You understand that by consenting to participate in the research, you are not giving up any of your legal rights (other than the postponement of your access to certain health information as described in this informed consent form);
(7) You understand that you have the right to be informed of significant new findings related to this research study which may affect your willingness to continue participating in this study;and
(8) You have been provided with a copy of the "Experimental Subject's Bill of Rights", if applicable to this research study, and have been provided with an opportunity to ask questions regarding the Bill of Rights.

We will give you a copy of this signed and dated consent form and the Experimental Subject's Bill of Rights.

SIGNATURE PAGE

Consent Form for Research

SIGNATURE BY THE PARTICIPANT: *I hereby agree to participate in the research study described to me during the informed consent process and described in this informed consent form.* ***You will be given a signed copy of this form.***

Name of Participant (Print)	Signature	Date Signed

Optional Medallia LivingLens Sub-study: *I agree to take part in the optional sub- study described to me during the informed consent process and in this document.*

Participant name (please print)	Signature	Date

Authorization for Use and Disclosure of Identifiable Health Information (Research)): *I hereby agree that my identifiable health information may be used and/or disclosed in accordance with this "Authorization for Use and Disclosure of Identifiable Health Information (Research)" form attached as Appendix to this form.*

Name of Participant (Print)	Signature	Date Signed

Optional Medallia LivingLens Sub-study Authorization: *I hereby agree that my identifiable health information may be used and/or disclosed for the optional sub-study in accordance with the "Authorization for Use and Disclosure of Identifiable Health Information (Research)."*

Participant name (please print)	Signature	Date

SIGNATURE BY THE INVESTIGATOR: *I attest that all the elements of informed consent described in this form have been discussed fully in non- technical terms with the participant. I further attest that all questions asked by the participant were answered to the best of my knowledge.*

Name of Investigator (Print)	Signature	Date Signed

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APPENDIX: EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

In accordance with California Health and Safety Code 24172, any person who is required to consent to participate as a subject in a research study involving a medical experiment or who is requested to consent on behalf of another has the right to:

1. Be informed of the nature and purpose of the experiment.

2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.

3. Be given a description of any attendant discomforts and risks to the subject reasonablyto be expected from the experiment.

4. Be given an explanation of any benefits to the subject reasonably to be expected fromthe experiment, if applicable.

5. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks andbenefits.

6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.

7. Be given an opportunity to ask any questions concerning the experiment or the procedure involved.

8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.

9. Be given a copy of any signed and dated written consent form used in relation to the experiment.

10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, orundue influence on the subject's decision.

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AUTHORIZATION FOR USE AND DISCLOSURE OF IDENTIFIABLE HEALTH INFORMATION FOR RESEARCH

- **USE AND DISCLOSURE OF HEALTH INFORMATION**

If you agree to this Authorization, you give permission to the research team at Cedars-Sinai Medical Center ("CSMC") to use or disclose your identifiable health information ("private information") for the research study titled "Hypertension Control and Remote Blood Pressure Monitoring" which is described in the Consent Form for Research ("Consent Form") to which this Authorization is attached. In particular, you authorize the research team acting under the direction of the Principal Investigator to review your medical records and collect your private information from the following sources:

☒ Laboratory tests
☐ Pathology reports
☐ Imaging reports (e.g., x-rays or scans)
☒ Photographs or videos of your image
☐ Demographics, which may include age, gender identity, race, ethnicity, and/or sexual orientation
☒ Doctor/clinic records
☒ Hospital/medical records
☐ Mental health records
☒ Billing records
☒ Other tests or other types of medical information: MEMS-cap Data
And Wisepill Data

- **WHO WILL HAVE ACCESS TO YOUR PRIVATE INFORMATION?**

Your private information will be used by and/or shared with the CSMC investigators listed in Section A of the Consent Form and their research staff.

In addition to the research team, if applicable, the following parties may receive your private information and inspect your records:

- The reviewing Institutional Review Boards and CSMC offices with authority to oversee research compliance.
- U.S. government agencies, such as the Food and Drug Administration and the Department of Health and Human Services.
- Researchers at other organizations who are participating in this research study.
- The Study Sponsor and its business partners, for matters related to research study oversight, data analysis and use of research results in product development.

- Representatives from regulatory agencies in other countries may join in the review of your research records, including research-related medical reports and information, with the Sponsor and/or the FDA.

CSMC is required by law to protect your private information. However, the recipients described above may re-disclose (or share) your information with other parties unless such sharing is prohibited by law.

- **WHEN WILL MY AUTHORIZATION EXPIRE?**

By signing this document, you authorize the use and sharing of your private information until the end of the research study.

- **REVOKING AUTHORIZATION**

You may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, the research team may still use or disclose private information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. To revoke this Authorization, you must write to the Principal Investigator of the research study. The mailing address is: Joseph Ebinger, MD, MS, Cedars-Sinai Medical Center, Smidt Heart Institute, 8700 Beverly Blvd, AHSP 3100, Los Angeles, CA 90048.

- **NOTICE OF RIGHTS AND OTHER INFORMATION**

You do not have to agree to this Authorization, but if you do not agree, you may not participate in the research study. CSMC may not condition (withhold or refuse)

treating you on whether you agree to this Authorization.

If you agree to this Authorization, please sign on the appropriate signature line below. You will receive a copy of this Authorization.

- **OPTIONAL SUB-STUDY**

In addition to the main research study, you have the option to agree to participate in one or more optional sub-studies as explained to you during the informed consent process. Your decision to take part in the optional sub-study(ies) does not impact your ability to participate in the main research study.

If you agree that your identifiable health information may be used and/or disclosed for the optional sub-study described in the informed consent process and above, you will be required to sign a second time in the signature section.

Medallia LivingLens Optional Sub-Study

Introduction
You are being provided with this information to consider taking part in an optional sub-study. **You can decline to take part in this optional sub-study. You can still be in the main study whether you are in the sub-study or not. Your medical care at Cedars-Sinai will not be changed in any way because of your decision.**

Before you decide, you should read the rest of this optional sub-study section. You can also ask the study team any questions to help you understand the sub-study. If you agree to take part in the sub-study, you will be asked to sign the sub-study signature lines on the Signature Page.

A. Purpose of Optional Sub-Study

We are collecting patient video or audio diaries about their daily experience with taking medication for hypertension to better understand how to help patients stick to their medication regimens.
Diaries can focus on any aspect of their experience with pill taking, including success stories or reasons for failing to take medication. The diary content will help our team of researchers to understand the patients' emotions and environments in which they take their medication, and how these environments help or distract them in sticking to their pill taking routine.

B. Optional Sub-Study Procedures
If you opt to participate in this video/audio diary substudy, you will be asked to complete the following tasks:

- You will need to have access to the internet in order to participate in this sub-study.
- During the first three weeks of the study, we will prompt you via email once a week to submit a diary, although you may also record and submit a diary whenever you feel like communicating with the research team.
- The weekly prompts may also be accompanied by a question asking you to rate your satisfaction with the study experience or with your progress in thestudy.
- When recording the video diary of your experience with the pill taking routine, you may choose to record your face while talking or point the camera to other relevant elements of your environment, for example where and how you store your pills, the objects that may remind you to take your pills, any issues in your environment that may prevent you from taking your pills on time.
- If you are uncomfortable with filming yourself or your location, you may place the recording device camera down on a surface and make an audio-only recording.
- After completing and uploading your diary entries, you may contact the research team to ask for a video to be deleted if you are uncomfortable with yoursubmission.
- After completing and uploading your videos, you may contact the research team to ask for part of your face or screen to be blurred to hide your or someone else'sidentity.

- The content of your video diaries will be transcribed using automated transcription software within the Medallia LivingLens Suite.
- Only the authorized research team will have access to these video diaries for data management, analysis, and editing purposes.
- The recordings will not include your name, or any of your medical information. Videos may mention your age and sex.
- The recordings will be used primarily for analysis by the research team; possible use as a teaching tool to those who are not members of the research staff (i.e., for educational purposes).
- We may also wish to present some of the diary segments at scientificconferences.
- For the duration of the study, the recordings will be stored on a secure, encrypted server to which access is password-protected.
- After the study is completed, recordings will be migrated to Cedars Sinai Medical Center servers.
- After the study is completed, we may contact you to ask you about your experience with the video recording.

Please indicate whether you consent to each of the following:

_____*I agree that segments of the recordings made of my participation in this research may be used for conference presentations, as well as education and training of future investigators/practitioners.*

_____*I agree to have my recordings archived for future research in the field of hypertension medication adherence.*

C. Length of This Optional Sub-Study

Your direct participation in the optional sub-study will last three weeks from the start of the study.

D. Possible Risks or Discomforts of This Optional Sub-Study

We collect information, including personal information that you voluntarily provide to us when you choose to participate in this video diary sub-study. When you use this interactivetool while connected to the Internet, there may be some risk(s) to your privacy. This risk is comparable to the risk of using other apps on your phone or laptop. If you are uncomfortable with recording your own image, you may make audio-only recordings to share with the team instead.

We are careful to ensure that the information you voluntarily provide to us is as secure as possible; however, you must be aware that transmissions over the Internet cannot be guaranteed to be completely secure.

Your study data will be stored in the cloud. “In the cloud” refers to servers in a data center that are managed by a third party and accessible through the Internet. When storing your study data, we will replace your name with a random code on all your study data.

We take great care to protect your information; however, there is a slight risk of loss of privacy. This is a low risk because we code your data by separating your personal information (information that can directly identify you, such as your name, email, or phone number) from the research study data. Only a few members of the research team are allowed to see your identifiable information. All others will only be able to see your coded information. The information that is obtained in connection with this substudy and that can be identified with you will remain confidential and will be disclosed only with your permissions or as required by law. The information collected about you will be coded using an assigned code with letters and numbers, and the information which has your identifiable information will be kept separately from the rest of your data.

Accidental public disclosure may occur such as unintended data breaches by hacking or other activities outside of the procedures authorized by the study. In such a case, your data may be misused or used for unauthorized purposes.

E. Benefits of This Optional Sub-Study

You should not expect to benefit from taking part in this sub-study.

While no benefit is ever guaranteed, we hope the information learned from this optional sub-study will benefit other individuals with the condition being studied in the future.

F. Payment

You will not be paid for taking part in this sub-study.

APPENDIX: FLOWCHART OF PROCEDURES – Medicare Coverage Analysis (MCA) Review

LEGEND
R = Research item/procedure done only for research purposes and covered by the study
S = Standard of care item/procedure that is part of regular care and billed to the patient/insurance

Aims 1-3

Activity	Screening and In-Person Visit	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
Informed Consent	R								
Medical History and Demographics	S								
Concomitant Medications	S	S	S	S	S	S	S	S	S
Enrollment into My CSLink	R								
Daily/Weekly Home Blood Pressure Medication-taking Monitoring and upload data		R	R	R	R	R	R	R	R
Phone Call to Patient			R	R	R	R	R	R	R
Medication Titration (as clinically indicated)		S	S	S	S	S	S	S	S
Laboratory Testing (as clinically indicated)		S	S	S	S	S	S	S	S
Discharge from Study									

Aims 4a-4b

Activity	Screening and In-Person Visit	Month 1	Month 2	Month 3	Post Month 3	Month 9
Informed Consent	R					
Medical History and Demographics	S					
Concomitant Medications	S	S	S	S	S	S
Randomization	R					
Follow Up Visit		R	R	R	S	R
Use of MEMS-Cap (used by participants when taking their regularly prescribed medications at home)		R	R	R	R	R
Prize Drawing (intervention group 3 only)		R	R	R		
Text Messages (intervention groups 2 and 3 only)		R	R	R		
Surveys	R	R	R	R		R
Laboratory Testing (as clinically indicated)		R	R	S		S
Medallia LivingLens Survey (sub-study)	R At least once a week (or more often as desired) for the first 3 weeks.	R				
Discharge from Study						R

APPENDIX: Detailed Description of Common Medical Procedures Performed for Research Purposes and Associated Risks

The procedures listed below are often performed as part of routine care for a person with your condition. They are being repeated or performed more frequently as part of this research. However, the risks associated with each procedure should be comparable to what you would experience even if you were undergoing the procedure outside this research study.

Study Procedure	Related Risks
Physical Exam: Includes height, weight, vital signs (heart rate and blood pressure)	There are no physical risks associated with these procedures.
Concomitant Medications: You will be asked about your previous and current medications that you take.	There are no physical risks associated with these procedures.
Medical History Review: You will be asked about your medical and surgical history with attention to [*Insert as appropriate*: smoking and alcohol habits, menopausal history (females only) and your physical activity]	There are no physical risks associated with this procedure.
Demographic Information: You will be asked about your age, gender, race, ethnicity	There are no physical risks associated with these procedures.