Principal Investigator: Steven R. Simon, MD

Title: A Technology-Assisted Care Transition Intervention for Veterans with Chronic Heart Failure or Chronic Obstructive Pulmonary Disease (Patient Consent Form)

1. Purpose of study: You are invited to participate in a research project designed to examine ways to support the transition from hospital to home and reduce urgent care and rehospitalization for Veterans with Chronic Heart Failure or Chronic Obstructive Pulmonary Disease. You have been invited because you are a Veteran with Chronic Heart Failure or Chronic Obstructive Pulmonary Disease.

This study is funded by the Department of Veterans Affairs Health Services Research & Development Division. We plan to enroll 200 participants in this study in VA Boston. Two other sites are also enrolling 200 subjects each.

2. Description of the study, procedures to be used, and how long it will last:

You will receive standard medical care as expected.
If you decide to participate in this research study, you will be randomized to receive one of two interventions to support your transition back to home. As part of the study design, you will not know which group you are in.

We will ask you to complete a 10 minute survey at the start of the study about your demographics, health, and pre/discharge experience. You will receive a short (20 minute) education on care transitions, and brief text messages related to this topic after you go home.

We will survey you over the phone two times about your experiences with the intervention. We will contact you 7 and 30 days after you leave the hospital for these surveys. The surveys will take about 30 minutes to complete. After you complete the survey at 30 days, you may be one of a small number of participants who are also invited to tell us more about your intervention experiences in a follow-up, 30-minute, audio-recorded phone interview. We will also collect Corporate Data Warehouse administrative records about your VA healthcare and usage statistics for VA technologies. Your participation will last about 30 days following your discharge from the hospital.

3. Reasonably foreseeable discomforts or inconveniences of the study:
You may experience some anxiety thinking about your conditions. You may find some of the questions uninteresting. You may become annoyed when interacting with the intervention. You can refuse to answer questions or can choose to withdraw from the study at any time.

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4. Reasonably foreseeable risks of study:
Confidentiality of Information: Participation in any research may involve a loss of privacy. Your research records will be kept as confidential as possible. Only a code number will link to your research records. The code number will not be based on any information that could be used to identify you (for example, social security number, initials, birth date, etc.) The master list linking names to code numbers will be kept separately from the research data.

All research information will be kept in locked files at all times. Your identity will not be revealed in any reports or publications resulting from this study. Only authorized persons will have access to the information gathered in this study. Federal Agencies such as the Office for Human Research Protection (OHRP), Government Accountability Office (GAO) and Food and Drug Administration (FDA) may have access to the records.

The Department of Veterans Affairs (VA) requires some information to be recorded in the VA electronic medical record for all veteran and non-veteran research subjects. Therefore, if you participate in this study, a medical record will be created if you do not already have one. Notes from your visits, procedures, and laboratory tests will be included in this record. We will make a note in your medical record that you participated in this study. In addition to the research team, and the VA staff who provide clinical services, other researchers may be granted approval to access this information in the future. Federal laws and regulation that protect privacy of medical records will apply to your VA record."

The treatment or procedure may involve risks that are currently unforeseeable.

5. Expected benefits of study:
There are no known direct benefits to you for being in this study.

6. Other treatment available:
The alternative to the intervention that we will be studying in this project is usual care including the VA's efforts to provide the best care for the transition from hospital to home.

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7. Use of research results and Confidentiality:

Data collected for the purpose of this research study will be kept confidential as required by law. The results of this study may be published for scientific purposes, but your records or identity will not be revealed unless required by law. Full measures will be taken to ensure the confidentiality of your identity as well as the confidentiality of all collected data.

Information about you is protected in the following way. All information about you that is gathered during the research, including audio recordings, will be coded without the use of personally identifiable information. Audio recordings will be transcribed to analyze content and identify key themes, via a certified transcription service which meets all VA security standards. The audio recordings will only be released outside the VA if this transcription service is outside the VA. A master list matching your personal information with your research code will be kept separate from your personal information in a locked file cabinet inside a locked office. All data will be stored on a private drive on a secure VA server. The data will be also be stored in the Annie Implementation Data Repository, a new data repository being set up at the ENRM VA Hospital, for future research studies pertaining to care transitions and augmented texting systems. All data will be stored and maintained according to VA regulations and only investigators approved through the data repository committee will have access to this data. Any future use of the data will be reviewed and approved by this committee. The creation and management of this data repository will be approved by the hospital Research and Development Committee before any of the data from this study will be stored in it for future use.

All research information will be kept in locked files at all times. Your identity will not be revealed in any reports or publications resulting from this study. Only authorized persons will have access to the information gathered in this study. Federal Agencies such as the Office for Human Research Protection (OHRP), Government Accountability Office (GAO) and Food and Drug Administration (FDA) may have access to the records. The Department of Veterans Affairs (VA) requires some information to be recorded in the VA electronic medical record for all veteran and non-veteran research subjects. Therefore, if you participate in this study, a medical record will be created if you do not already have one. Notes from your visits, procedures, and laboratory tests will be included in this record. In addition to the research team, and the VA staff who provide clinical services, other researchers may be granted approval to access this information in the future. Federal laws and regulation that protect privacy of medical records will apply to your VA record.

Subject's Name: _____ , _____ **Date:** _____
Last First

Soc. Sec. No. _____

(If research requires documentation in the medical record in accordance with VHA handbook 1907.1 the entire SSN must be obtained. If research does not require documentation in the medical record the SSN should not be obtained)

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If results of this study are reported in medical journals or at meetings, you will not be identified by name, by recognizable photograph, or by any other means without your specific consent. Your medical records will be maintained according to VA requirements.

Your research records will be kept indefinitely or until the law allows their destruction in accordance with the VA Record Control Schedule (www1.va.gov/VHAPUBLICATIONS/RCS10/rcs10-1.pdf). Records will be destroyed, when allowed, in the following manner.

- Paper records will be shredded
- Electronic records will be destroyed in a manner in which they cannot be retrieved.
- Digital images (photographs, x-rays, scans, video/audio recordings, etc) will be destroyed in a manner in which they cannot be retrieved.

Your data will be entered into a data repository and used for future studies approved by an IRB.

8. New Findings:

You will be told of any significant new findings that come to light during the course of this study and that may relate to your wanting to stay in the study.

9. Special circumstances: A veteran subject will not be required to pay for medical care and services received as a subject in an approved VA research study. Some veterans are required to pay co-payments for medical care and services provided by the VA. These co-payment requirements will continue to apply to medical care and services (including, but not limited to, dental services, supplies, medicines, orthopedic and prosthetic appliances, and domiciliary or nursing home care) provided by the VA that are not part of this research study

There will be no additional medical costs to you as a result of your participation in this study.

You will be given a $30 gift card for your participation in this research project as soon as your participation is complete. Payments will be mailed to your home within 2 weeks of participation.

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Receiving and responding to text messages as part of this study may result in **charges** billed by the phone company if you do not have a cellular phone plan that includes text messaging (typically up to $0.20 per message). If you do not have a cellular phone plan that includes text messaging, you will be reimbursed for your text messaging costs with an additional $5 or $15 gift card depending on the costs incurred.

10. Rights of Recourse: In the event that you are injured as a result of your being in this research study, you will receive medical care, including emergency treatment. This care or treatment is governed by federal law and VA policy. You would also have the right to file any legal action, as in any instance of alleged negligence.

11. Study Monitoring: You consent to the access of your VA research and medical records that may identify you by persons approved for this purpose. Such access may be by the Human Studies Subcommittee and Research Oversight Committees of this hospital, the VA, federal agencies, national research oversight and accreditation organizations. You may expect the same confidentiality from these persons that is given to you by the Investigator and his/her research staff.

12. RESEARCH SUBJECT'S RIGHTS: I have read or have had read to me all of the above. The study person named below has explained the study to me and answered all of my questions. I have been told of the discomforts and risks of the study. I have been told of other choices of treatment that I could have.

I understand that if I have any medical questions about this research study, I can call **Dr. Steven Simon** at **(774) 826-2450** during normal working hours.

I understand that if I have any general questions about this research study, I can call **Rachel Wacks** at **(781) 687-3361** or **Carolyn** Purington at **(781) 687-4737** during normal working hours.

I understand that if I have any medical problems that might be related to this study that **during the day** I can call **Dr. Steven Simon** at **(774) 826-2450** and **after hours** I can call **the Medical Center operator at (617) 232-9500** and ask for Dr. Simon to be paged.

Subject's Name: _____ , _____ **Date:** _____
Last First

Soc. Sec. No. _____

(If research requires documentation in the medical record in accordance with VHA handbook 1907.1 the entire SSN must be obtained. If research does not require documentation in the medical record the SSN should not be obtained)

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I understand that, if at any point during or after this study I have any questions about my rights as a research subject or I want to discuss problems, complaints, concerns, and questions about the research, obtain information, or offer input, I may contact the Research Compliance Officer at (857) 364-4182.

I understand that my participation in this study is voluntary, that I do not have to take part in this study and that, if I do take part, I may withdraw from the study at any time. I also understand that, if I refuse to take part or if I decide to withdraw, I will not suffer any penalty, loss of rights, or loss of VA or other benefits that I have a right to receive.

I voluntarily consent to be in this study. I will receive a signed copy of this consent form.

Subject's Signature	**Month Day Year**	**Name (print)**
Signature of Person Obtaining Consent	**Month Day Year**	**Name (print)**

Signature of Subject's Legally Authorized Representative	**Month Day Year**
Name (print)	

Subject's Name: _____ , _____ **Date:** _____
Last First

Soc. Sec. No. _____

(If research requires documentation in the medical record in accordance with VHA handbook 1907.1 the entire SSN must be obtained. If research does not require documentation in the medical record the SSN should not be obtained)

VA Boston IRB # _____

Approval Period: _____